United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

EPA 738-R-00-023
October 2000

Reregistration Eligibility Decision (RED)

Vinclozolin

United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

EPA-738-F-00-021
October 2000

EPA R.E.D. FACTS

Vinclozolin

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. To implement provisions of the Food Quality Protection Act of 1996, EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet the safety standard of the FQPA and can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 2740, vinclozolin.

Use Profile

Vinclozolin is a fungicide used to control various diseases on raspberries, chicory grown for Belgian endive, lettuce, kiwi, canola, snap beans, dry bulb onions, ornamentals, and turf. Import tolerances have been established to permit importation of vinclozolin-treated cucumbers, sweet peppers and wine. Vinclozolin is formulated as a dry flowable and extruded granular which may be applied with aerial, chemigation, or ground equipment (broadcast, band, or soil drench); as a dip treatment on ornamental bulbs and corms, cut flowers, rose budwood, or nursery stock; and with thermal foggers in greenhouses.

Regulatory History

Vinclozolin has been registered in the United States since 1981 for use as a fungicide. A Data Call-In (DCI) was issued in 1991 for vinclozolin requiring the submission of additional data on product and residue chemistry, toxicity, environmental fate, and ecological effects. Subsequent DCIs were issued in 1995 and 1996 requiring additional environmental fate and ecological toxicity studies. Also, the Agricultural Data Call-In (AGDCI) was issued in 1995, which required data to help estimate postapplication occupational exposure. The Reregistration Eligibility Decision (RED) reflects a reassessment of all data which were submitted in response to the DCIs.

In April 1997, the risks from all uses were reevaluated under the Food Quality Protection Act (FQPA) when a new use for this chemical was proposed by BASF Corporation (succulent beans). The estimated dietary cancer risks were above the level generally regarded as negligible. As a result, previously registered uses were voluntarily canceled by the registrant and the Agency has revoked the related tolerances, namely for tomatoes, plums, prunes, and grapes (except wine grapes). To reduce exposure to children, residential uses of vinclozolin were deleted and turf and ornamental applications limited to commercial and industrial sites. Following this mitigation, a three-year time-limited tolerance was established for succulent beans in 1997.

In June 1998, after EPA's decision to retain the FQPA safety factor of 10X, BASF requested voluntary cancellation of its vinclozolin uses on stone fruits and strawberries to reduce dietary exposure to vinclozolin residues. The Agency published a Federal Register notice announcing the use deletions on July 30, 1998. At that time, BASF also requested use rate reductions for turf and agreed to phase out its liquid formulations, as well as phase-in water soluble packaging for the remaining formulations. Revocation of the stone fruit and strawberry tolerances will be proposed in an upcoming Federal Register notice.

On July 18, 2000 the Agency established 3 year time-limited tolerances for vinclozolin and its metabolites containing the 3,5-DCA moiety on succulent beans, canola, eggs, milk, and the meat, fat, and meat byproducts of cattle, goats, hogs, horses and sheep. In order to mitigate risk associated with the added uses, EPA accepted a proposal submitted by the registrant which includes the following actions to occur over the next 4 years: A phase out of all domestic food uses of vinclozolin except for use on canola, and revocation of all import tolerances except for wine grapes. The Agency published the proposed use deletions in the Federal Register

for public comment on September 20, 2000 (65 FR 56894, FRL-6744-2). On September 18, 2000, EPA received objections to the newly-issued tolerances on succulent beans and canola. Once EPA finalizes its response to the objections, it will amend its reregistration and reassessment decisions, if any such amendment is necessary.

In addition to the use cancellations, BASF also initiated measures at that time to mitigate risks identified through the reregistration process including cancellation of the use on ornamental plants due to postapplication risk concerns and new restrictions on turf use based on non-dietary risks to children. Use on sod farm turf was prohibited (except for transplant onto golf courses) and application to turf was restricted to golf courses and industrial sites.

In an effort to promote transparency and public acceptance in regulatory decision making, the Agency, in cooperation with the U.S. Department of Agriculture (USDA), is working to modify the reregistration process. Until a final process is established, an interim process is being used to provide opportunities for stakeholders to ask questions and provide input on risk assessments and risk mitigation strategies, via conference calls and other formats. Consistent with this process, a conference call was conducted on June 1, 2000 with EPA, USDA, the registrant, and other stakeholders (e.g., growers, commodity groups, land grant universities) to discuss the basis of the calculated risks of vinclozolin, the Agency's risk concerns, and the registrant's voluntary cancellation and phase-out proposal. Also, a close-out conference call was conducted on September 25, 2000 with many of the same participants from the June 1st conference call, to discuss the additional risk management decisions and resultant changes to the vinclozolin labels.

Human Health Assessment

Toxicity

Vinclozolin generally has been shown to have low acute oral/dermal/inhalation toxicity. Vinclozolin is not an irritant to the eye/skin but can act as a skin sensitizer. The principal toxic effects induced by vinclozolin and/or its metabolites are related to its antiandrogenic activity. Androgens are the principal male steroid hormones, such as testosterone, which stimulate the development and maintenance of the male reproductive system and secondary sex characteristics. Studies show that vinclozolin may have minimal antiandrogenic activity at relevant dose levels but that at least two vinclozolin metabolites occur in mammals, plants, and soil and are responsible for much of the antiandrogenic activity attributable to vinclozolin. Vinclozolin exerts its effects most dramatically during the developmental stages of

animals ultimately resulting in reproductive effects. At low dose levels in rats (>3 mg/kg/day), the most androgen sensitive effects are noted, such as decreased prostate weight, weight reduction in other sex organs, nipple/areolas development, and decreased ano-genital distance in male rats. At higher dose levels, the reduction in male sex organ weight is exacerbated, and sex organ malformations are seen, such as reduced penis size, ectopic testes, vaginal pouches, hypospadias, and additional ambiguities of the urogenital system. In some studies reduced fertility from the hypospadias, delayed puberty and kidney stones were noted. Since the androgen receptor is widely conserved across species lines, anti-androgenic effects would be expected in humans. However, the human consequence of many of the low dose effects in male rats such as reduced ano-genital distance, areola and nipple development, and reduced prostate weight is unknown. Vinclozolin and/or its metabolites cause Leydig cell (testicular) tumors in rats. There is also evidence in the published literature that vinclozolin may affect the development and function of the neuroendocrine system. The Agency has also determined that vinclozolin's terminal metabolite, 3,5-dichloroaniline (3,5-DCA), should be regulated based on potential carcinogenic concerns. 3,5-DCA is a common metabolite of two related fungicides, iprodione and procymidone.

Dietary Exposure

People may be exposed to residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety through the diet. Tolerances or maximum residue limits have been established in 40 CFR §180.380 for: succulent beans; Belgian endive tops; cucumbers; wine grapes; kiwifruit; leaf and head lettuce; dry bulb onions; bell peppers; raspberries; stonefruits except plums/fresh prunes; strawberries; canola; milk; cattle fat, meat, and meat byproduct; eggs; poultry fat, meat and meat byproduct; sheep fat, meat and meat byproduct; goat fat, meat and meat byproduct; hog fat, meat and meat byproduct; horses fat, meat, and meat byproduct.

The following tolerances do not need to be amended at this time: wine grapes, canola and the animal products associated with canola in feed. All other tolerances will be proposed for revocation within the next few years after use cancellation.

Risk From Food

For vinclozolin, acute, chronic and carcinogenic dietary risk from food is not of concern. Cancer dietary risk from 3,5-DCA in food is also not of concern ($<1 \times 10^{-6}$).

Risk From Food + Drinking Water

Model estimates of potential drinking water exposure from ground and surface water sources are not of concern for vinclozolin. Based on screening-level models, carcinogenic dietary risk from vinclozolin-derived 3,5-DCA in drinking water is above the Agency's level of concern. 3,5-DCA exhibits fate properties (high mobility and persistence) of pesticides which may be found in ground and surface waters.

Risk From Non-dietary Exposure

There are no vinclozolin pesticide products registered for use by homeowners. Vinclozolin can, however, be occupationally used in a manner that may lead to post-application exposures to golfers playing on treated golf courses and homeowners and their families coming into contact with or playing on sod which has been previously treated on a sod farm. No chronic exposures or exposures of sufficient duration to cause cancer were identified. The short-/intermediate-term risk to golfers of all age ranges is below the Agency's level of concern. Risks to toddlers playing on treated sod fall beneath the Agency's level of concern 24 days after application. To mitigate the unacceptable risk resulting from exposure before the 24 day period has elapsed, the registrant has submitted label amendments deleting use on sod farms (except for transplant onto golf courses), and has begun the immediate restickering of all product in the channels of trade to require a 24 day period before sod can be harvested. Although the Agency's level of concern would have been exceeded, the risk reduction measures implemented by the registrant immediately reduce risk such that it is below the Agency's level of concern.

Aggregate Risk

The short- and intermediate-term aggregate risk assessment includes exposure from nonoccupational settings in addition to the dietary (food and water) exposure. When aggregating food and water exposure with toddler's exposure to treated sod, the sod pre-harvest interval (PHI) of 24 days results in short- and intermediate-term aggregate risk below the Agency's level of concern. Food, water, and adult/child golfer exposure do not exceed the Agency's level of concern when aggregated.

EPA also considered the relative contribution of vinclozolin-, iprodione- and procymidone-derived 3,5-DCA. The aggregate food-only cancer risk associated

with 3,5-DCA derived from **all three** of these imide fungicides is not of concern ($<1 \times 10^{-6}$). However, the vinclozolin- and iprodione-derived 3,5-DCA EECs alone exceed the carcinogenic aggregate DWLOC indicating a potential for concern.

Occupational Risk

Workers can be exposed to vinclozolin during handler activities such as mixing, loading, applying and flagging, or by re-entering treated sites. Occupational risk estimates were not considered for onions, raspberries and ornamentals because the registrant has requested immediate cancellation. Only one handler scenario, applying with an airblast sprayer (kiwi), indicates the need for an increase in protection beyond current label requirements. Lettuce, kiwi and turf pose a postapplication risk concern, i.e., the Agency does not believe that the currently labeled REIs are of sufficient duration to protect workers from exposure to residues of concern.

FQPA Considerations

EPA has determined that the established tolerances for vinclozolin, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of vinclozolin residues in this population subgroup.

In determining whether infants and children are particularly susceptible to toxic effects from vinclozolin residues, EPA considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. For vinclozolin, the FQPA safety factor of 10 was **retained** because: (1) there is evidence of increased susceptibility to offspring following *in utero* exposure to vinclozolin in the prenatal developmental toxicity study in rats; and (2) a developmental neurotoxicity study in rats with an expanded protocol is required for vinclozolin due to concern for the antiandrogenic properties of vinclozolin and its metabolites.

In accordance with the Food Quality Protection Act (FQPA), the Agency is examining whether, and to what extent, some or all members of the imide group of

the dicarboximide class of fungicides, which include vinclozolin, iprodione and procymidone, share a common mechanism of toxicity. Although there are data suggesting that these dicarboximide fungicides induce some of the same antiandrogenic effects, the mechanism by which they cause these toxic effects has not been adequately evaluated. As a result, the Agency has not determined if it would be appropriate to include them in a cumulative risk assessment. In addition, there may be other compounds outside of this class of fungicides that may also be considered antiandrogenic. Therefore, for the purposes of this risk assessment, the Agency has assumed that vinclozolin does not share a common mechanism of toxicity with the dicarboximide fungicides or other possible antiandrogens.

Environmental Assessment

Environmental Fate

Vinclozolin dissipates in the environment by microbial-mediated hydrolysis, soil metabolism, abiotic degradation, and transport with water. Metabolite B is a common degradate of hydrolysis, soil metabolism, and photolysis. The other principal degradation products of vinclozolin are 3,5-dichloroaniline and metabolite E, which appears to be a degradation product of parent and metabolite B. Metabolite E degrades to 3,5-dichloroaniline. Experimental evidence has shown 3,5-DCA to be resistant to degradation processes.

Vinclozolin and its principal degradates are potentially very mobile to slightly mobile in soil. Metabolites B, E and 3,5-DCA may be transported with water through the soil profile or with surface runoff. Residues are likely to be most mobile in sandy soils low in organic matter.

In terrestrial field dissipation studies, vinclozolin dissipated with half-lives of 34 to 94 days. Half-lives for total residues (vinclozolin plus its dichloroaniline-containing metabolites) were 179 to >1000 days. Persistence of total residues appeared to be attributable to the resistance of 3,5-DCA to degradation and to the inclusion of soil-bound residues in the data. Intermittent detections of residues were reported at soil depths of 12-18, 18-24, and 24-30 inches. 3,5-DCA was detected regularly deeper than 6 inches. Residues may accumulate and be available for rotational crop uptake. Vinclozolin has a low potential to bioaccumulate in fish.

Ecological Effects

Results indicate that vinclozolin is practically nontoxic to birds, mammals, and honey bees on an acute basis. Vinclozolin is moderately toxic to freshwater/estuarine fish and freshwater/estuarine invertebrates on an acute basis.

Vinclozolin and/or its metabolites have been shown *in vitro* and *in vivo* to be potent mammalian anti-androgenic compounds, inhibiting androgen receptor binding and gene expression. In addition to the adverse effects observed in the male fetuses in the mammalian species, endocrine disruption effects in birds include reduced egg laying, reduced fertility rate, and reduced hatching successes.

Ecological Effects Risk Assessment

The risk assessment for vinclozolin indicates low levels of acute risk to wildlife. The Agency's level of concern has been exceeded for chronic effects to avian species for most use sites. The registrant has already requested the phase-out of all uses except turf and canola. For canola, all avian chronic RQs are below the level of concern assuming average use rates. For turfgrass, the highest RQ is 2.7, which is slightly above the LOC of 1.0. The registrant has undertaken several mitigation measures on turf during the last few years which reduce risk to nontarget species on turf. Chronic risk to aquatic organisms has not been assessed due to lack of data.

Risk Mitigation

BASF, the vinclozolin registrant, has already requested changes to its vinclozolin registrations, including the phase-out of most uses and new restrictions on turf use. In addition to these measures, EPA is recommending the following risk mitigation measures to lessen the risks posed by vinclozolin.

- To address drinking water concerns, the registrants of vinclozolin and iprodione should initiate a surface and ground water monitoring program. Ground water and surface water advisory language is warranted on vinclozolin product labels.
- Only the extruded granular formulation packaged in water soluble bags is eligible for reregistration.
- Labels should specify enclosed cabs for airblast applicators.
- An advisory statement should be added informing crop advisors to wear early entry PPE when entering treated sites during the REI.
- A label statement should be added to the 24(c) label for chicory informing employers of chicory root workers that they must ensure that workers in the chicory root spray area wear the PPE required for applicators. Employers must provide, clean, and maintain all PPE.
- The REI for kiwi should be increased from 24 hours to 6 days. The REI on sod farm turf should be increased from 12 hours to 5 days. The REI for lettuce should be increased from 12 hours to 7 days. An exception to the 7 day REI may be established for applications to lettuce taking place within

35 days of planting. Under this exception, workers may enter to perform some tasks after 24 hours.

- A double notification statement must be included on labels. Workers will be notified of applications orally and by posting.

Additional Data

The following additional generic studies for vinclozolin are necessary to confirm its regulatory assessments and conclusions:

The Agency has determined that a developmental neurotoxicity (DNT) study is warranted; however, the kinds of perturbations likely to occur with androgen/estrogen disruptor cannot be identified by the standard guideline DNT study. Consequently, the DNT study will be due 3 years after the Agency determines the protocol necessary to assess the relevant endpoints.

In additional to the water monitoring data, environmental fate studies will be requested in order to better understand the persistence and mobility of the degradates. Some ecotoxicity studies were required in a previous DCI and are still outstanding. The registrant is in the process of submitting the studies.

Product Labeling Changes

All vinclozolin end-use products should comply with EPA's current pesticide product labeling requirements and with the label changes outlined in the RED document.

Regulatory Conclusion

The use of currently registered products containing vinclozolin in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration. This decision takes into consideration the registrant's request to cancel most currently registered uses of vinclozolin.

Vinclozolin products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for vinclozolin during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide

Docket, Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805. Electronic copies of the RED and this fact sheet are available on the Internet. See http://www.epa.gov/REDs. Printed copies of the RED and fact sheet can be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695. Following the comment period, the vinclozolin RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 1-800-553-6847, or 703-605-6000.

For more information about EPA's pesticide reregistration program, the vinclozolin RED, or reregistration of individual products containing vinclozolin, please contact the Special Review and Reregistration Division (7508C), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000. For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticide Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 PM Pacific Time, or 9:30 am to 7:30 PM Eastern Standard Time, seven days a week. Their Internet address is **ace.orst.edu/info/nptn.**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

NOV 21 2000

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the risk assessment for the fungicide vinclozolin. Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of vinclozolin. EPA is now publishing its reregistration eligibility, risk management, and tolerance reassessment decisions for the current uses of vinclozolin, and its associated human health and environmental risks. The Agency's decision on the individual chemical vinclozolin can be found in the attached document entitled, "Reregistration Eligibility Decision for Vinclozolin" which was approved on September 29, 2000.

A Notice of Availability for this Reregistration Eligibility Decision (RED) for Vinclozolin is published in the *Federal Register*. To obtain a copy of the RED document, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the RED and all supporting documents are available on the Internet (**www.epa.gov/pesticides**).

This document and the process used to develop it are the result of a pilot process to facilitate greater public involvement and participation in the reregistration and/or tolerance reassessment decisions for pesticides. As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), the Agency is undertaking a special effort to maintain open public dockets and to engage the public in the reregistration and tolerance reassessment processes for these chemicals. In cooperation with the U.S. Department of Agriculture, the Agency held a teleconference on June 1, 2000, during which the results of the human health and environmental effects risk assessments were presented to interested stakeholders. Information discussed during the call, such as vinclozolin usage and occupational practices, are reflected in this RED. Also, a close-out conference call was conducted on September 25, 2000 with many of the same participants from the June 1 conference call, to discuss the risk management decisions and resultant changes to the vinclozolin labels.

Please note that the vinclozolin risk assessment and the attached RED concern only this particular fungicide. Vinclozolin is a member of the imide group of the dicarboximide class of fungicides, as are iprodione and procymidone. While current data are limited, EPA has certain evidence that these compounds may modulate androgens by a common mechanism of toxicity. Because of the complexity of the androgen system, a careful evaluation is needed before a formal decision can be made. At this time, the Agency does not believe it has sufficient reliable information concerning common mechanism issues to determine whether or not vinclozolin shares a common mechanism of toxicity with iprodione and/or procymidone. Therefore, for the purposes of this risk assessment, the Agency has assumed that vinclozolin does not share a common mechanism of toxicity with the other imide fungicides. The Agency did consider the contribution of each of these related pesticides to the cumulative risk resulting from exposure to 3,5-DCA which is a metabolite common to all three compounds.

End-use product labels need to be revised by the manufacturer to adopt the changes set forth in Section IV of this document. Instructions for registrants on submitting revised labeling and the time frame established to do so can be found in Section V of this document.

If you have questions on this document or the proposed label changes, please contact the Special Review and Reregistration Division representative, Deanna Scher at (703) 308-7043. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Jane Mitchell at (703) 308-8061.

Lois A. Rossi

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

REREGISTRATION ELIGIBILITY DECISION for VINCLOZOLIN

Case No. 2740

TABLE OF CONTENTS

Vinclozolin Reregistration Eligibility Decision Team

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Steve Nako	Economic Analysis Branch
Istanbul Yusuf	Economic Analysis Branch

Environmental Fate and Effects Risk Assessment

Dirk Young	Environmental Risk Branch IV
Nick Federoff	Environmental Risk Branch IV
Dana Spatz	Environmental Risk Branch IV
Daniel Balluff	Environmental Risk Branch IV

Health Effects Risk Assessment

William Hazel	Reregistration Branch I
Elizabeth Mendez	Reregistration Branch I
Jeff Dawson	Reregistration Branch I
Felecia Fort	Reregistration Branch I
David Anderson	Reregistration Branch II

Registration Support

Mary Waller	Fungicides Branch
Carl Grable	Fungicides Branch

Risk Management

Deanna Scher	Reregistration Branch I
Mark Wilhite	Reregistration Branch I
John Leahy	Reregistration Branch I

Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level

OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1^*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

Executive Summary

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of vinclozolin, as well as the tolerance reassessment decision for vinclozolin, which includes the consideration of risk to infants and children for any potential dietary, drinking water, dermal or oral exposures. The Agency made its reregistration eligibility determination based on the data required for reregistration, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that all registered uses of vinclozolin are eligible for reregistration provided specified changes are made to labels. This decision takes into account the registrant's request to cancel most currently registered uses of vinclozolin.

Use Summary

Vinclozolin is a non-systemic fungicide currently registered in the United States for use on raspberries, chicory grown for Belgian endive, lettuce, kiwi, canola, succulent beans, and dry bulb onions. Import tolerances have been established to permit importation of vinclozolin-treated cucumbers, sweet peppers, and wine (from treated grapes), but there are no U.S. registrations for these uses. Vinclozolin is also registered for use on ornamentals and turf.

BASF, the manufacturer of vinclozolin, has requested the phase-out of the following uses: onions, raspberries and ornamentals immediately; kiwi and chicory in December 2001; and lettuce and snap beans in July 2004. BASF will also request revocation of the import tolerances to cover residues in/on peppers and cucumbers in January 2001. After 2004, only use on canola, non-domestic wine grapes, and turf will remain. These use cancellations and tolerance revocations allowed the Agency to establish tolerances for vinclozolin in/on canola and snap beans in July, 2000. The Agency published the proposed use deletions for public comment in the Federal Register on September 20, 2000 (65 FR 56894, FRL-6744-2). On September 18, 2000 EPA received objections to the new tolerances established for vinclozolin in/on succulent beans and canola. Once EPA finalizes its response to the objections, it will amend its reregistration and reassessment decisions if necessary.

Labels have also been recently amended to prohibit use on turf except for golf courses and industrial park landscapes and to prohibit use on sod except for transplant onto golf courses. BASF has restickered all sod products bearing old labels to add a 24 day pre-harvest interval to sod harvested for residential and commercial transplant.

Vinclozolin can be applied as a foliar spray with aerial, ground and handheld equipment, and through chemigation. It is formulated (trade names: Ronilan, Curalan, Vorlan, Touche) as a 50% dry flowable or as a 50% extruded granule in water soluble packets (both under EPA Reg. No. 7969-85). In 1998, BASF requested voluntary cancellation of the 41% liquid flowable (FL) product (7969-62) and the wettable powder (WP) product (7969-53). A minimal amount of these formulated products may still exist in the channels of trade. Registered products containing vinclozolin are not currently classified as restricted use.

Toxicity

The Agency has reviewed all toxicity studies and has determined that the toxicity database is complete. However, pursuant to FQPA, a modified developmental neurotoxicity study is necessary to confirm potential neuroendocrine effects from vinclozolin. The principal toxic effects induced by vinclozolin are related to its antiandrogenic activity and its ability to act as a competitive antagonist at the androgen receptor, ultimately resulting in developmental effects in test animals. There is evidence that vinclozolin binds fairly weakly to the androgen receptor but that at least two vinclozolin metabolites occurring in mammals, plants, and soil are responsible for much of the antiandrogenic activity attributable to vinclozolin.

Vinclozolin is classified as a Group C chemical (possible human carcinogen). Vinclozolin induces a hormonally-mediated increase in Leydig cell tumors in rats in what appears to be a threshold response. The chronic Population Adjusted Dose (cPAD) has been used to express carcinogenic risk. The Agency believes that the use of the cPAD for "overall antiandrogenic" effects is protective of cancer effects because it is protective of the precursor antiandrogen effects which lead to tumor formation.

The terminal metabolite of vinclozolin, 3,5-dichloroaniline (3,5-DCA) is considered to have a genotoxic mode of tumor induction based on its similarity to its structural analog parachloroaniline, which is carcinogenic in animal carcinogenicity studies. 3,5-DCA is also a common metabolite of two related fungicides, iprodione and procymidone.

Dietary Risks

Acute, chronic, and overall antiandrogenic (carcinogenic) dietary risks from food are not of concern to the Agency. The Agency's dietary exposure assessments were somewhat refined by the use of anticipated residues from field trial data and percent of crop treated data. A Monte Carlo probabilistic analysis was used for the acute dietary risk assessment. Acute, chronic, and overall antiandrogenic/carcinogenic drinking water concentrations were also estimated to evaluate the contribution of drinking water to dietary risk. These drinking water estimates are based on ground and surface water computer models.

A cancer dietary risk assessment using a low-dose linear extrapolation was conducted on 3,5-dichloroaniline (3,5-DCA), the terminal metabolite of vinclozolin in plants, animals, and soil. The 3,5-DCA cancer risk from food due to vinclozolin exposure is below the Agency's level of concern; however, water modeling indicates possible carcinogenic risk concerns from environmental concentrations of 3,5-DCA in surface water and ground water. Additional environmental fate and monitoring data are needed to evaluate risk from 3,5-DCA in surface and ground water.

Non-occupational Risks

There are no vinclozolin pesticide products registered for use by consumers; however, vinclozolin use may lead to post-application exposures to the general population, specifically to golfers playing on treated golf courses and homeowners and their families coming into contact with sod previously treated on a sod farm. There are no risk concerns for adult and child golfers; however, risk to children playing on treated sod is of concern. The registrant has effectively mitigated this risk with a label amendment to allow use on sod farms only for sod intended for transplant onto golf courses, and by restickering all sod products already in the channels of trade to require a 24-day period before treated sod can be harvested for placement in residential areas.

Aggregate Risks

Aggregate acute, chronic, and carcinogenic risk is not of concern for vinclozolin. Short- and intermediate-term aggregate risks would have exceeded the Agency's level of concern because the residential component alone, toddler exposure to treated sod, exceeds the Agency's level of concern. In response, the registrant implemented mitigation measures; specifically, eliminating residential sod use and stickering product in the channels of trade to prohibit use on residential sod, which bring the risk below the Agency's level of concern.

For vinclozolin-derived 3,5-DCA, the cancer dietary (food) risk estimate of 2.6×10^{-7} associated with all currently registered uses is not of concern. However, both the ground and surface water estimated concentrations exceed the 3,5-DCA carcinogenic drinking water level of concern.

The Agency considered the relative contribution of vinclozolin, iprodione, and procymidone to multichemical, aggregated carcinogenic dietary risk resulting from exposure to 3,5-DCA, which is a metabolite common to some extent to all three compounds. The combined food-only cancer risk associated with 3,5-DCA derived from all three fungicides does not exceed the Agency's level of concern. Drinking water risk from vinclozolin- and iprodione-derived 3,5-DCA is of concern. Water monitoring studies will be called-in for both chemicals.

Cumulative Risk

In accordance with the Food Quality Protection Act (FQPA), the Agency is examining whether, and to what extent, some or all members of the imide group of the dicarboximide class of fungicides, which include vinclozolin, iprodione and procymidone, share a common mechanism of toxicity. The Agency does not currently have a fully developed understanding of whether vinclozolin shares a common mechanism of toxicity with iprodione and procymidone because the androgen system is highly complex. As a result, the Agency has not determined if it would be appropriate to include them in a cumulative risk assessment. Therefore, for the purposes of this assessment, the Agency has assumed that vinclozolin does not share a common mechanism of toxicity with iprodione and procymidone.

Occupational Risks

An enclosed cab requirement for airblast applicators is necessary to reduce short- and intermediate-term risk to handlers. Post-application risk is of concern for lettuce, kiwi, and sod farm turf at currently labeled restricted entry intervals. Increased REIs are necessary for these crops to reduce short- and intermediate-term risk to post-application workers.

Ecological Risks

In addition to the human health effects, the Agency assessed ecological risks potentially caused by the use of vinclozolin. Overall, ecological risk concerns exist but the exceedences are relatively low. Specifically, chronic levels of concern are slightly exceeded for birds assuming average use rates. Chronic risk to aquatic organisms has not been assessed due to lack of data. These data have been required in a previous Dall Call-In and the registrant is in the process of submitting studies.

More detailed information can be found in the technical supporting documents for vinclozolin referenced in this RED document. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page **(www.epa.gov/pesticides)**, and in the Public Docket.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require EPA to review all tolerances in effect on the day before the date of the enactment of the FQPA by the year 2006. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including an assessment of the cumulative effects of chemicals with a common mechanism of toxicity.

The Food Quality Protection Act requires that the Agency consider the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency is examining whether and to what extent the imide group of the dicarboximide class of fungicides modulate androgens by a common mechanism of toxicity. The androgen system may be modulated in different ways including competitive binding to androgen receptors, interference with gene control over the synthesis of several enzymes or other factors associated with synthesis of androgens. All of these variables relate to the potency, specificity, and site of action of the antiandrogen and determine the expression of the antiandrogenicity induced by various compounds. Because of the complexity of the androgen system, a careful evaluation of all the available data is still needed, as well as peer review by the FIFRA Science Advisory Panel, before a formal decision is made regarding whether or not these compounds modulate androgens by a common mechanism of toxicity. Therefore, for the purposes of this risk assessment, the Agency has assumed that vinclozolin does not share a common mechanism of toxicity with other members of the imide group of the dicarboximide class of fungicides.

Similarly, the Agency is examining whether and to what extent some pesticides that may be carcinogens may also share a common mechanism of toxicity. Current information on the common mechanism of toxicity for possible or probable human carcinogens is limited, and the Agency's understanding of this relationship needs to be further developed. As a result, the Agency has not determined if it would be appropriate to include them in a cumulative risk assessment with other carcinogen chemicals.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of vinclozolin, including the consideration of risk to infants and children for any potential dietary,

drinking water, dermal or oral exposures, and cumulative effects as stipulated under the FQPA. In an effort to simplify the RED, the information presented herein is summarized. More detailed information can be found in the technical supporting documents for vinclozolin referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page **www.epa.gov/pesticides**, and in the Public Docket. This document consists of six sections. Section I is the introduction. Section II provides a profile of the use and usage of vinclozolin, and its regulatory history. Section III gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV presents the reregistration eligibility and risk management decisions. Section V describes what registrants need to do in order to be eligible for reregistration. Finally, the Appendices list all related documents and Data Call-In (DCI) information.

II. Chemical Overview

A. Regulatory History

Vinclozolin has been registered in the United States since 1981 for use as a fungicide. A Data Call-In (DCI) was issued in 1991 for vinclozolin requiring the submission of additional data on product and residue chemistry, toxicity, environmental fate, and ecological effects. Because vinclozolin is a List B chemical, no Registration Standard was prepared. Subsequent DCIs were issued in 1995 and 1996 which required additional environmental fate and ecological toxicity studies. Also, the Agricultural Data Call-In (AGDCI) was issued in 1995, requiring data to develop restricted entry intervals for workers. This Reregistration Eligibility Decision (RED) reflects a reassessment of all data which were submitted in response to the DCIs.

In April 1997, the risks from all uses were reevaluated under the Food Quality Protection Act (FQPA) when a new use for this chemical was proposed by BASF Corporation (succulent beans). The estimated dietary cancer risks were above the level generally regarded as negligible. As a result, previously registered uses were voluntarily canceled by the registrant and the Agency has revoked the related tolerances, namely for tomatoes, plums, prunes, and grapes (except wine grapes). At the request of BASF, to reduce exposure to children, residential uses of vinclozolin were deleted and turf and ornamental applications limited to commercial and industrial sites. As a result of this mitigation, a three-year time-limited tolerance was established for succulent beans in 1997.

In June 1998, after EPA's decision to retain the FQPA safety factor of 10X, BASF requested voluntary cancellation of its vinclozolin uses on stone fruits and strawberries to reduce dietary exposure to vinclozolin residues. The Agency published a Federal Register notice announcing the use deletions on July 30, 1998. At that time, BASF also requested use rate reductions for turf and agreed to phase out its liquid formulations, as well as phase-in of water soluble packaging for the remaining formulations. Under the existing stocks provision, vinclozolin could have been used on strawberries and stonefruits until January 30, 2000. Revocation of the stone fruit and strawberry tolerances will be proposed in an upcoming Federal Register notice.

On July 18, 2000 the Agency established 3 year time-limited tolerances for vinclozolin and its metabolites containing the 3,5-DCA moiety on succulent beans, canola, eggs, milk, and the meat, fat, and meat byproducts of cattle, goats, hogs, horses and sheep[1]. The decision of whether or not to grant the tolerances was outside the scope of this RED, and was made separately by the Agency. In order to mitigate risk associated with the added uses, EPA accepted a proposal submitted by the registrant which includes the following items to occur over the next 4 years: A phase out of all domestic food uses of vinclozolin except for use on canola, revocation of all import tolerances except for wine grapes; and cancellation of the use on ornamental plants[2]. BASF also submitted label amendments to prohibit use on sod farms except for transplant of treated sod onto golf courses; and to restrict turf use to golf courses and industrial sites. In addition, as a short-term risk reduction measure, label amendments were approved on June 14, 2000 to add a 24-day pre-harvest interval for sod harvested for placement in residential areas by stickering vinclozolin products used on sod that have already been packaged and/or sold by BASF. BASF has not shipped any material from their warehouses without stickers since June, 2000 and mailed stickers to their warehouses and the distribution chain in July, 2000.

On September 18, 2000, EPA received objections to the newly-issued tolerances on succulent beans and canola from the Natural Resources Defense Council, the Environmental Working Group, Pineros y Campesinos Unidos Del Noroeste, and Northwest Coalition for Alternatives to Pesticides [hereinafter referred to as "Objectors"]. These objections challenged the use of anticipated residue values and percent crop treated information in acute risk assessments generally and also questioned the reliability of the specific percent crop treated data pertaining to use of vinclozolin on succulent beans. The Objectors had filed similar comments with EPA prior to issuance of the tolerances and EPA considered them in granting these tolerances. EPA will carefully evaluate these objections, paying particular attention to any new legal arguments or facts advanced, and respond as required by law. However, EPA does not believe these objections merit any delay in release of this reregistration decision and tolerance reassessment. Once EPA finalizes its response to the objections, it will amend its reregistration and reassessment decisions, if any such amendment is necessary.

In an effort to promote transparency of the reregistration process and public acceptance of regulatory decisions, the Agency, in cooperation with the U.S. Department of Agriculture (USDA), is working to modify the reregistration process. An interim process has been established to provide opportunities for stakeholders to ask questions and provide input on the risk assessment and risk mitigation strategies, via conference calls and other formats. See Chapter IV Section B for a detailed description of the modified process. Consistent with this process, a conference call was conducted on June 1, 2000 with EPA, USDA, the registrant, and other stakeholders (e.g., growers, commodity groups, land grant universities) to discuss the basis of the calculated risks of vinclozolin, the Agency's risk concerns, and the registrant's voluntary cancellation and phase-out proposal. Also, a close-out conference call was

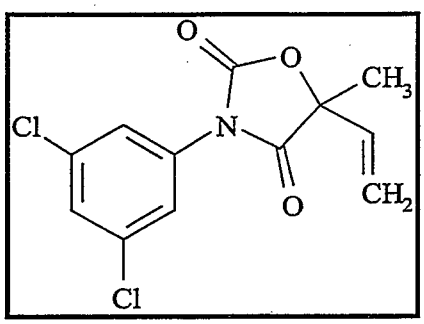
---

1. Canola growers in North Dakota and Minnesota were able to use vinclozolin in 1998 through Section 18 exemptions.

2.The decision to cancel use on ornamental plants was based on occupational concerns, unrelated to the evaluation of the tolerance decisions.

conducted on September 25, 2000 with many of the same participants from the June 1st conference call, to discuss the additional risk management decisions and resultant changes to the vinclozolin labels.

a. Chemical Identification: Vinclozolin



Vinclozolin is a colorless to white crystalline solid with a melting point of 108° C. Technical vinclozolin is slightly soluble in water (<1 g/kg), and more soluble in benzene (146 g/kg), ethyl acetate (253 g/kg), chloroform (319 g/kg), and acetone (435 g/kg). Vinclozolin hydrolyzes slowly in alkaline solutions.

- **Common Name:** Vinclozolin
- **Chemical Name:** 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione
- **Chemical Family:** Carboximide fungicide
- **CAS Registry Number:** 50471-44-8
- **OPP Chemical Code:** 113201
- **Empirical Formula:** $C_{12}H_9Cl_2NO_3$
- **Vapor Pressure:** 2.6×10^{-6} torr
- **Trade Name:** Ronilan®, Curalan®, Vorlan®, Touche®
- **Basic Manufacturer:** BASF Corporation

B. Use Profile

The following is information on the currently registered uses including an overview of use sites and application methods. A detailed table of the uses of vinclozolin eligible for reregistration is contained in Appendix A.

Type of Pesticide

Vinclozolin is a non-systemic fungicide used to control various blights and rots caused by fungal pathogens.

Use Sites

Vinclozolin is registered in the United States for use on raspberries, chicory grown for Belgian endive, lettuce, kiwi, canola, snap beans, and dry bulb onions. Import tolerances have been established to permit importation of vinclozolin-treated cucumbers, sweet peppers, and wine, but there are no U.S. registrations for these uses. Vinclozolin can also be applied to ornamentals and turf. There are no residential uses for vinclozolin products.

BASF, the manufacturer of vinclozolin, has proposed to immediately eliminate or phase-out uses such that only use on canola and turf will remain after 2004. The Agency agreed to BASF's requests and published the above use changes for public comment on September 20, 2000. BASF also requested that the Agency propose to revoke the import tolerances to cover residues in/on peppers and cucumbers.

Other Label Restrictions

Not for use in Florida
Special Local Needs Registrations [FIFRA §24(c)] for kiwi and chicory in California only

Target Pests

Species of *Alternaria, Bipolaris, Botrytis, Ciborinia, Drechslera, Fusarium, Colletotrichum, Helminthosporium, Laetisaria, Lanzia, Limonomyces, Microdochium, Moellerodiscus, Monilinia, Ovulinia, Rhizoctonia, Sclerotinia, Sclerotium,* and *Stomatinia.*

Formulation Types

Vinclozolin is formulated as a 50% extruded granule (EG) sold only in water-soluble packets and as a 50% dry flowable (DF) formulation for open pour. In 1998, BASF requested voluntary cancellation of the 41% liquid flowable (FL) product and the wettable powder (WP) product. A minimal amount of these formulated products may still exist in the channels of trade.

Method and Rates of Application

Vinclozolin may be applied with aerial, chemigation or ground equipment (broadcast, band, or soil drench); as a dip treatment on ornamental bulbs and corms, cut flowers, rose budwood, or nursery stock; and with thermal foggers in greenhouses. Handheld equipment may be used on turf and ornamentals. Application to chicory grown for Belgian endive is a post-harvest treatment prior to cold

storage or forcing. *Agricultural* use rates vary depending on crop from 0.33 to 1.00 lb a.i./acre, applied 1 to 5 times per season; maximum seasonal application rate is 5 lbs a.i./acre (on onions). *Ornamental* use rates vary depending on application method and range from 0.0025 lb a.i./gallon to 0.0 15 lbs a.i./gallon with 10 to 14 day intervals between applications. The maximum single event application rate on *turf* is 1.35 lb a.i./acre with a maximum seasonal rate of 4.0 lb a.i./acre.

Use Classification
General Use Pesticide

C. Estimated Usage of Pesticide

Table 1 below summarizes the best available estimates for the pesticide uses of vinclozolin. An estimated 141,000 pounds a.i. are applied annually in the U.S. After the phase-out of several uses is completed in 2004, the Agency expects the annual usage to drop to 71,000 pounds a.i. per year. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

Table 1. Vinclozolin Usage Summary

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)	
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max
Food Sites							
Chicory /*	2	--	--	0%	10%	--	--
Kiwifruit	7	2	3	26%	42%	2	3
Lettuce, Total	280	37	52	13%	19%	33	46
Lettuce, Head	190	36	48	19%	25%	32	42
Lettuce, Other	90	1	4	1%	5%	1	4
Onions, Dry	144	1	6	1%	4%	1	6
Snap Beans, Total /*	223	39	84	17%	38%	21	47
Snap Beans, Fresh	68	0	7	0%	10%	0	4
Snap Beans, Proc.	155	39	78	25%	50%	21	43
Canola /*	1,450	54	290	4%	20%	21	??
Raspberries	11	5	6	43%	52%	6	7
Non-Food Sites:							
Golf Courses						50	60
Horticultural Nurseries						2	5
Commercial Turf/Ornamentals						5	10
Imports:							

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)	
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max
	Imports: % of US Consumption	% of Imported Crop Treated					
		Weighted Average		Estimated Maximum			
Endive, Imports /*		10%		30%		100%	
Grape/Wine, Imports		17%		5%		10%	
Kiwi Imports /*		45%		5%		100%	
Cucumbers		40%		<1%		1%	
Peppers		29%		<1%		1%	

COLUMN HEADINGS

Wtd Avg = Weighted average--the most recent years and more reliable data are weighted more heavily; Est Max = Estimated maximum, which is estimated from available data; Average application rates are calculated from the weighted averages.

NOTES ON TABLE DATA Calculations of the above numbers may not appear to agree because they are displayed as rounded to the nearest 1000 for acres treated or lb. a. i., and to the nearest whole percentage point for % of crop treated. Therefore 0 = < 500; and 0% = < 0.5%. 0* = Available EPA sources indicate that no usage is observed in the reported data for this site, which implies that there is little or no usage. A dash (-) indicates that information on this site is NOT available in EPA sources or is insufficient (100%CT may be used for risk assessment purposes).

/* SPECIAL NOTES Chicory: Vinclozolin was not applied to California chicory in 1995/1996. California has about 1,200 acres, over 50% of the US total (1992 Ag Census). Canola: Likely Maximums are based on information submitted in Section 18 requests (99ND08); actual use has not reached these levels. Endives: Approximately 10% of the endives consumed in the US are imported from Brussels, and several other countries. Endives/Kiwi: The 100% Likely Maximum %CT for Imports is due to the limiting nature of the Landell Mills pesticide use data for these crops.

SOURCES: USDA (1990-97), California EPA\DPR (1995-96), Certified\Commercial Pesticide Applicator Survey (1993), Foreign Agricultural Trade of the US (1994), Agricultural Statistics (1998), & various proprietary data sources, including: Doane (1988-98), Mike Buckley (1994-97), SRI (1993), National Center for Food and Agricultural Policy (1992), Kline (1990-97), and Landell Mills (1993-97).

III. Summary of Vinclozolin Risk Assessment

The following is a summary of EPA's human health and ecological risk findings and conclusions for the fungicide vinclozolin, as presented fully in the documents, "Vinclozolin - Revised Human Health Risk Assessment" dated May 12, 2000, "EFED Reregistration Eligibility Summary for Vinclozolin" dated June 6, 1996 and "Errata for Terrestrial Assessment of Revised Uses" dated December 21, 1999. Since the completion of the revised risk assessment, the Agency has calculated new estimated environmental concentrations (EECs) and drinking water levels of comparison (DWLOCs) for vinclozolin and 3,5-dichloroaniline (3,5-DCA). The Agency has also revised the post-application risk estimates for workers. The risk assessments and risk mitigationa measures presented in the RED considered stakeholder input.

The purpose of this decision document is to summarize the key features and findings of the risk assessment in order to help the reader better understand the risk management decisions reached by the

Agency. While the risk assessments and related addenda are not included in this document, they are available on the Agency's web page (www.epa.gov/pesticides), and in the Public Docket. Public comment was solicited on the revised risk assessment and the Agency invited all interested stakeholders to submit risk mitigation proposals. The risk assessment and risk mitigation measures presented in this RED considered stakeholder input.

A. Human Health Risk Assessment

1. Dietary Risk from Food

a. Toxicity

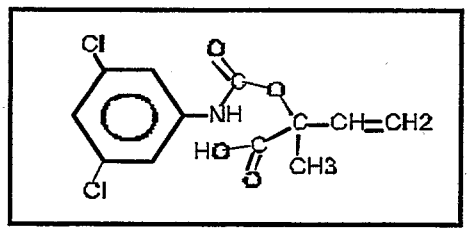
The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is sufficiently complete, with the exception of a modified developmental neurotoxicity study, and that it supports a reregistration eligibility determination for all currently registered uses.

The principal toxic effects induced by vinclozolin and/or its metabolites are related to its antiandrogenic activity and its ability to act as a competitive antagonist at the androgen receptor. Androgens are the principal male steroid hormones, such as testosterone, which stimulate the development and maintenance of the male reproductive system and secondary sex characteristics. Vinclozolin exerts its effects most dramatically during the developmental stages of animals ultimately resulting in reproductive effects; it also interferes with lipid metabolism and/or storage. Androgen receptor inhibition in the rat represents a constellation of effects on androgen dependent organs and functions. At low dose levels (>3 mg/kg/day), the most androgen sensitive effects are noted, such as decreased prostate weight, weight reduction in other sex organs, nipple/areolas development, and decreased ano-genital distance in male rats. At higher dose levels, the reduction in male sex organ weight is exacerbated, and sex organ malformations are seen, such as reduced penis size, ectopic testes, vaginal pouches, hypospadias, and additional ambiguities of the urogenital system. In some studies reduced fertility from the hypospadias, delayed puberty and kidney stones were noted. Since the androgen receptor is widely conserved across species lines, anti-androgenic effects would be expected in humans. However, the human consequence of many of the low dose effects in male rats such as reduced ano-genital distance, areola and nipple development, and reduced prostate weight is unknown. There is also evidence in the published literature that vinclozolin may affect the development and function of the neuroendocrine system.

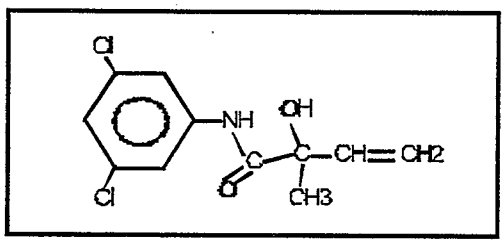
Vinclozolin and/or its metabolites cause Leydig cell (testicular) tumors in rats via an antiandrogenic mechanism as opposed to a direct genotoxic mode of action. In the pituitary gland, inhibition of androgen receptors results in increased luteinizing hormone which in turn may aid unknown factors to stimulate the testicular Leydig cells.

There is evidence that vinclozolin binds fairly weakly to the androgen receptor but that at least two vinclozolin metabolites occurring in mammals, plants, and soil are responsible for much of the antiandrogenic activity attributable to vinclozolin. These metabolites, known as M1 (also Metabolite B)

and M2 (Metabolite E), have both undergone cleavage of the oxazolidine ring (see structures below). M1 is a reversible hydrolysis product and M2 is an irreversible product following the loss of a carbon atom from the oxazolidine ring. The relative androgen receptor binding affinity, determined by the ability to displace a known steroidal androgen receptor binding agent in vitro, is M2>Ml>Vinclozolin.



M1 or metabolite B



M2 or metabolite E

Vinclozolin has low acute toxicity as evidenced by the Toxicity Categories of III or IV associated with oral, dermal, eye, and inhalation exposure. It does act as a dermal sensitizer. Acute oral toxicity is classified as a Toxicity Category IV, based on test results that indicate the LD_{50} (males and females) $\geq$10,000 mg/kg; (MRID No. 00080451 and 92194010).

The Agency has determined that only vinclozolin and its terminal metabolite 3,5-dichloroaniline (3,5-DCA) should be regulated and assessed for dietary exposure in plant commodities. The decision to regulate on the 3,5-DCA metabolite is based on potential carcinogenic concerns. 3,5-DCA has not been tested for carcinogenicity in animal studies, however, it may have carcinogenic properties because it is related to the structural analog parachloroaniline, which is carcinogenic in animal carcinogenicity studies. Although the untested 3,5-DCA is less reactive than parachloroaniline, the data are insufficient to quantitatively determine how much less reactive in carcinogenicity studies. Therefore, 3,5-DCA is regulated based on the carcinogenic potential of parachloroaniline.

Further details on the toxicity of vinclozolin can be found in the *Hazard Characterization* section of the May 12, 2000 Human Health Risk Assessment and the December 8, 1999 Second Report of the Hazard Identification Assessment Review Committee.

b. FQPA Safety Factor

The FQPA Safety Factor is intended to provide up to an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food or to compensate for an incomplete database. The FQPA Safety Factor for the protection of infants and children (as required by FQPA) has been **retained (10X)** for all exposure durations. The rationale for retention of the 10X FQPA Safety Factor is: (i) there is evidence of increased susceptibility to offspring following *in utero* exposure to vinclozolin in perinatal developmental studies in rats. Note that the effect on male sex organ weights seen in the perinatal studies were observed at one or more dose levels in the chronic studies used to establish the chronic RfD; and (ii) a developmental neurotoxicity study in rats is required for vinclozolin due to concern for the antiandrogenic properties of vinclozolin and its metabolites. There is evidence that compounds like vinclozolin may disrupt the neuroendocrine system

through their anti-androgenic properties leading to changes in the morphological and biochemical development of the nervous system.

Details regarding the retainment of the FQPA Safety Factor can be found in the EPA memorandum dated December 15, 1999 entitled, *Vinclozolin: Reassessment Report of the FQPA Safety Factor Committee.*

c. Hazard Determination

The doses, toxicity endpoints selected, and supporting studies for various dietary exposure scenarios are summarized in Table 2.

Acute Dietary
The acute dietary risk assessment has been conducted only on females of child-bearing age because this toxicity endpoint is an *in utero* effect. Adverse effects applicable to other subpopulations and resulting from a single dose were not observed. The No Observed Adverse Effect Level (NOAEL), adjusted for a single dose, was 6 mg/kg/day from an oral developmental rat study. Decreased ventral prostate weight in male offspring occurred at the adjusted Lowest Observed Adverse Effect Level (LOAEL) of 11.5 mg/kg/day. This effect is the most sensitive indicator of acute antiandrogenic developmental toxicity. The total uncertainty factor is assessed at 1000X (10X for interspecies extrapolation, 10X for intraspecies variation, and the 10X FQPA factor). Division of the NOAEL by this total uncertainty factor results in a Population Adjusted Dose (aPAD)[3] for females 13-50 of 0.006 mg/kg/day.

Chronic (Non-Cancer) Dietary
Effects observed at the LOAEL of 2.3 mg/kg/day in rat oral chronic/carcinogenicity studies include histopathological lesions of the lungs, liver, ovaries, and eyes. The NOAEL was 1.2 mg/kg/day. As in the case of acute dietary, the total uncertainty factor is 1000X, resulting in a cPAD of 0.0012 mg/kg/day.

Cancer Dietary
Vinclozolin is classified as a Group C chemical - possible human carcinogen based on Leydig (interstitial testicular) cell tumors in chronic and carcinogenicity studies. The development of the Leydig cell tumors are probably related to the antiandrogenic activity of vinclozolin and some related hormonal or cellular imbalance. A nonlinear (MOE) approach was initially determined to be appropriate based on a weight of the evidence conclusion that tumor induction is via an antiandrogenic mechanism. However, the Agency has recently determined that use of the most sensitive toxicity endpoint and the full 10X FQPA Safety factor is protective of the antiandrogenic effects on all populations caused by vinclozolin **including carcinogenic effects.**[4] The most sensitive toxicity endpoint/dose and safety

---

[3] The Population Adjusted Dose (PAD), is a relatively new term that reflects the Reference Dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA Safety Factor.

[4] See May 9, 2000 Reassessment Report of the FQPA Safety Factor Committee.

factor are derived from the rat oral chronic/carcinogenicity study, i.e., the NOAEL of 1.2 mg/kg/day and an uncertainty/safety factor of 1,000. Use of the chronic PAD (0.0012 mg/kg/day) is protective of cancer effects because it is protective of the precursor antiandrogen effects which lead to tumor formation.

Cancer Dietary from Vinclozolin-derived 3,5-DCA

A low-dose linear extrapolation (Q_1*) was conducted on 3,5-dichloroaniline resulting solely from the use of vinclozolin. EPA assumes the carcinogenic potential of all chloroanilines is the same as that of p-chloroaniline unless there is sufficient evidence that the chloroaniline in question is either not carcinogenic or is of a different potency than p-chloroaniline, for which a Q_1* of 6.38×10^{-2} $(mg/kg/day)^{-1}$ has been calculated. The dietary risk due to vinclozolin-derived 3,5-DCA vinclozolin was also aggregated with 3,5-DCA risks associated with the use of two related fungicides, iprodione and procymidone which also have 3,5-DCA as a terminal metabolite.

Table 2. Summary of Vinclozolin Dietary Toxicity Endpoints and Other Factors Used in the Human Health Risk Assessment of Vinclozolin and 3,5-DCA

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary (Females 13+)	NOAEL=6.0 UF = 100 FQPA SF = 10	Decreased ventral prostate weights in offspring at the adjusted LOAEL of 11.5 mg/kg/day.	Perinatal Developmental Toxicity - Rat MRID 44395701 & 44395702
	Acute RfD = 0.06 mg/kg/day Acute PAD = 0.006 mg/kg/day		
Acute Dietary (Adult Males, Infants, & Children)	This assessment is not required. There were no toxicological effects applicable to these populations and attributable to a single exposure (dose) observed in oral toxicity studies including the developmental toxicity studies in mice, rats, and rabbits.		
Chronic (Non-cancer) Dietary	NOAEL=1.2 UF = 100 FQPA SF = 10	Histopathological lesions in the lungs (males), liver (males), ovaries (females) and eyes (both sexes) at the LOAEL of 2.3 mg/kg/day.	Combined Chronic Toxicity/Carcinogenicity-Rat MRID 43254701 -702, - 703
	Chronic RfD = 0.012 mg/kg/day Chronic PAD = 0.0012 mg/kg/day		
Carcinogenic dietary risks have been calculated using two approaches: (1) Overall Antiandrogenic Approach, and (2) the MOE approach			
Overall Antiandrogenic Effects (Carcinogenic Dietary)	NOAEL=1.2 UF = 100 FQPA SF = 10	Antiandrogenic mode of action. The chronic NOAEL with an UF of 1,000 is protective of the developmental, reproductive, and carcinogenic effects of vinclozolin's antiandrogenicity. LOAEL = 2.3 mg/kg/day.	Combined Chronic Toxicity/Carcinogenicity-Rat MRID 43254701 -702, - 703
	Overall antiandrogenic effects RfD = 0.012 mg/kg/day Overall antiandrogenic PAD = 0.0012 mg/kg/day		
Carcinogenic Dietary for 3,5-DCA	Q_1* = 6.38×10^{-2} $(mg/kg/day)^{-1}$	The Q_1* is that of p-chloroaniline (PCA), assumed by EPA to be representative of all chloroanilines. The PCA Q_1* is based on the spleen sarcoma rate in male rats in an NTP study (Fisher, 1994).	

d. Exposure Assumptions

The dietary (food) exposure analysis is a fairly conservative Tier 3 approach utilizing the Dietary Exposure Evaluation Model (DEEM™). The DEEM™ analysis evaluated individual food consumption as reported by respondents in the USDA 1989-91 Continuing Surveys for Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity.

For all dietary analyses, anticipated residues (ARs) from field trial data and percent of crop treated data were used. FDA and USDA/PDP monitoring data are available for most foods expected to bear vinclozolin residues. These monitoring data are not useful because the programs do not analyze all vinclozolin metabolites containing the 3,5-DCA moiety. Field trial data on vinclozolin and its metabolites containing the 3,5-DCA moiety are available for all crops. The use of field trial data is considered conservative for the following reasons: (1) Field trial data assumes that all crops are treated at the maximum application rate and harvested at the minimum pre-harvest interval (PHI); (2) Field trial data assumes no decline between harvest and consumption of the crop; (3) Home processing was not accounted for in the risk assessment; and (4) For the acute dietary risk assessment, the vinclozolin metabolites of greatest concern are those closely related to the parent compound. Use of field trial data in the acute dietary assessment assumes that all residues have structures closely related to the parent compound and that they all elicit the developmental effects of concern. In reality, many metabolites convertible to 3,5-DCA may have structures different from parent such that they are not of acute concern.

Although vinclozolin use on strawberries and stone fruit was canceled in 1998, dietary assessments both with and without strawberries and stone fruits was conducted in the HED human health risk assessment since vinclozolin could have been applied to both of these crops until very recently (1-30-00) according to the existing stocks agreement. Since the uses are canceled and the last legal use date has expired, the dietary risk estimates presented in this document DO NOT include the dietary contribution from strawberries and stone fruits.

No processing factors were available; therefore, the DEEM default concentration factors were used. For more information on the parameters and assumptions used for assessing dietary risks, see the *Dietary Exposure* section of the May 12, 2000 Human Health Risk Assessment and the May 4, 2000 memo entitled, *Results of Revised Dietary Risk Assessment.*

e. Dietary (Food) Risk Assessment

Acute Dietary Risk

Acute dietary risk is calculated considering what is eaten in one day, in this instance, the full range of consumption values as well as the range of residue values in food. A risk estimate that is less than 100% of the acute Population Adjusted Dose (PAD) (the dose at which an individual could be exposed on any given day and no adverse health effects would be expected) does not exceed the Agency's level of concern. The acute PAD is the reference dose (RfD) adjusted for the FQPA safety factor.

A probabilistic (Monte Carlo) acute dietary analysis was conducted for vinclozolin. This analysis was a fairly conservative Tier 3 assessment due to the use of field trial residue data. Therefore, the Agency has assessed risk at the 99.9th percentile of exposure as well as below 99.9. The acute dietary exposure estimates for the only population subgroup of concern, females 13+, utilized the following percentage of the aPAD at the various percentiles of exposure, presented in Table 3.

Table 3. Acute Dietary Exposure and Risk Estimates (Food Only) for Females 13+[a]

Percentile of Exposure	Exposure (mg/kg/day)	%aPAD
99.9th	0.007196	120%
99.85th	0.005877	98%
99.8th	0.004987	83%
99.75th	0.004425	73%
99.6th	0.003316	60%
99.5th	0.002933	49%

[a] Exposure estimates include currently registered uses only. Use on strawberries and stone fruits has been canceled.

Assuming all currently registered foods are treated, including those which will be immediately canceled, acute dietary risk from vinclozolin in food is above the Agency's level of concern at the 99.9th percentile of exposure with 120% of the aPAD utilized. A sensitivity analysis was conducted in which the tail (>99.9th percentile of exposure or consumption) of the distribution were found to be comprised of 58% succulent beans and 26% onions. Risks at the 99.9th percentile of exposure are typically used for assessing risk when the exposure figures are highly refined. In this case, the exposure assessment is considered to be only somewhat refined as it represents the use of the full distribution of relevant field trial data (mean for the blended canola oil). EPA believes using the highest percentiles of exposure unreasonably overstates risk. At all but the very highest percentiles of exposure (99.85th and above), the %aPAD is below 100%. Upon completion of the registrant's phase-out plan in 2004, acute dietary risk from food will be well below the Agency's level of concern for females 13+ with 4% of the aPAD consumed at the 99.9th percentile of exposure.

Chronic (Non-Cancer) and Overall Antiandrogenic (Carcinogenic) Dietary Risk

Vinclozolin is classified as a Group C chemical (possible human carcinogen), based on Leydig (interstitial testicular) cell tumors in a perinatal rat developmental toxicity study. The PAD approach was used as the basis for risk characterization and risk management. Use of the cPAD for both chronic AND overall antiandrogenic (carcinogenic) risks is protective of human health because antiandrogenic activity is a prerequisite for hyperplasia and tumor formation. Chronic (non-cancer) and overall antiandrogenic (carcinogenic) dietary risk is calculated by using the average consumption values for food and average residue values for those foods over a 70-year lifetime. A risk estimate that is less than 100% of the chronic PAD (the dose at which an individual could be exposed over the course of a

lifetime and no adverse health effects would be expected) does not exceed the Agency's level of concern. The results of the analysis, based on all currently registered uses, are summarized in Table 4.

Table 4. Chronic/Overall Antiandrogenic Exposure and Risk Estimates (Food Only)

Subgroups	Exposure (mg/kg/day)	% cPAD
U.S. Population	0.000040	3%
Females (13+)	0.000034	3%
Children (1-6 years)	0.000078	7%
All infants (< 1 year)	0.000064	5%

As indicated in Table 4, the chronic (non-cancer and cancer) dietary risk (food) does not exceed the Agency's level of concern (<100% of the chronic PAD) for the general U.S. population and all subgroups. When all registered uses are assumed, exposure to the general U.S. population corresponds to 3% of the cPAD whereas the most exposed subgroup is children (1-6 years), with an estimated exposure corresponding to 7% of the cPAD. After completion of the phase-out period, chronic and cancer (overall antiandrogenic) risks to all population subgroups will be less than 1% of the cPAD. For more information on chronic dietary risk assessment, see the *Dietary Exposure and Risk Analysis* section of the May 12, 2000 Human Health Risk Assessment.

Carcinogenic Dietary Risk from 3, 5-DCA

The terminal metabolite of vinclozolin, 3,5-dichoroaniline (3,5-DCA) is considered to have a genotoxic mode of tumor induction based on its similarity to p-choroaniline. There have been no other toxic effects/doses identified for 3,5-DCA because, not being a pesticide, this chemical does not have a toxicity data base. The Q_1* used was 6.38 $x10^{-2}$ (mg/kg/day) established for p-chloroaniline based on the spleen sarcoma rate in male rats from an NTP bioassay. Cancer risk from 3,5-DCA was calculated using the average consumption values for food and average residue values for those foods over a 70-year lifetime. The chronic exposure value was combined with a linear low-dose approach (Q_1*) to determine the lifetime (cancer) risk estimate. Based on the worst-case estimate from plant metabolism studies that 10% of the total radioactive residues is comprised of 3,5-DCA, the Agency assumed that 10% of the total chronic dietary exposure based on field trails would consist of 3,5-DCA. Cancer risk was 2.6 $x10^{-7}$, which does not exceed the Agency's level of concern (1 x 10^{-6}). The food risk associated with combined human exposure to 3,5-DCA derived from vinclozolin, iprodione, and procymidone is presented in the Aggregate Risk section.

2. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through ground and surface water contamination. EPA considers acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or

actual monitoring data, if available, to estimate those risks. To determine the maximum contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a "drinking water level of comparison" (DWLOC) to ascertain whether or not modeled or monitoring estimated environmental concentrations (EECs) exceed this level. EECs that are above the corresponding DWLOC exceed the Agency's level of concern.

For vinclozolin, the available monitoring data are of limited use because the metabolite concentration measurements were not performed. In the absence of reliable, available monitoring data, EPA used models to calculate the EECs. Modeling is generally considered to be an unrefined assessment that may provide high-end estimates. Drinking water sources of 3,5-DCA derived from both vinclozolin and iprodione (procymidone is not registered for use in the U.S.) have been considered in the Aggregate Risk section.

The drinking water assessment for vinclozolin was conducted on: 1) vinclozolin plus the principal metabolites B and E and 2) the principal metabolites assumed to degrade completely to 3,5-DCA. Since the Agency lacks information on the persistence and mobility of metabolites B and E, the drinking water estimates serve to bracket the maximum concentration of the endocrine disrupting compounds associated with vinclozolin as well as the maximum concentration of total degradates available to degrade to 3,5-DCA in drinking water.

Environmental Fate

Laboratory and field data indicate that parent vinclozolin is relatively labile and dissipates in the environment by microbial-mediated hydrolysis, soil metabolism, abiotic degradation, and transport with water. Metabolite B is a common degradate of hydrolysis, soil metabolism, and photolysis. The other principal degradation products of vinclozolin are 3,5-DCA and metabolite E, a degradation product of parent and metabolite B. Other degradates are formed in smaller concentrations. Metabolite E degrades to 3,5-dichloroaniline, which appears to resist further degradation. Metabolites B, E and 3,5-DCA are potentially very mobile to slightly mobile and may be transported with water through the soil profile or with surface runoff. Residues are likely to be most mobile in sandy soils low in organic matter.

In terrestrial field dissipation studies conducted in FL, NY, MO, and CA, vinclozolin dissipated with modeled first-order half-lives of 34 to 94 days. Half-lives for total residues (vinclozolin plus its dichloroaniline-containing metabolites) were 179 to >1,000 days. Persistence of total residues appeared to be attributable to the resistance of 3,5-DCA to degradation and to the inclusion of soil-bound residues in the data. The Agency has no data on the degradation rates of B, E, or 3,5-DCA. Intermittent detections of residues were reported at soil depths of 12-18, 18-24, and 24-30 inches. 3,5-DCA was detected regularly deeper than 6 inches. Residues may accumulate and be available for rotational crop uptake.

Surface Water

Vinclozolin and its degradation products could be available for runoff for several weeks to months after application. Vinclozolin can be transported to surface water at application via spray drift from aerial and ground applications. For estimating surface water concentrations of vinclozolin and 3,5-DCA, EPA used GENEEC, a screening-level Tier I model. At present, PRZM-EXAMS, the Tier II model, does not have the appropriate parameters to accurately model turf run off. GENEEC, a less refined model, typically reports higher values than PRZM/EXAMS.

Ground Water

Because degradates of vinclozolin are mobile and can be persistent, the chemical has the potential to contaminate ground water. Risk estimates for vinclozolin and 3,5-DCA in ground water are based on Tier I SCI-GROW modeling. SCI-GROW provides a screening-level concentration which is an estimate of likely groundwater concentrations if the pesticide were used at the maximum allowed label rate in areas with groundwater vulnerable to contamination. In most cases, a majority of the pesticide use area will have groundwater that is less vulnerable to contamination than the areas used to derive the SCI-GROW estimate.

Drinking Water Risk Estimates

Due to the lack of persistence and mobility data for vinclozolin's degradation products, an individual analysis for each of the degradates was not performed. Instead, B and E were included in calculations for vinclozolin, and 3,5-DCA was used as a surrogate for all three major metabolites (B, E and 3,5-DCA). The results of the surface and ground water estimates from application to turf and their comparison with the DWLOCs are summarized in Table 5 for vinclozolin and Table 6 for 3,5-DCA.

For more information on drinking water risks and the DWLOC calculations, see the Water *Exposure section* of the May 12, 2000 Human Health Risk Assessment, the Environmental Fate and Effects Risk Assessment memo entitled *Vinclozolin and its Degradates* dated February 4, 1999, and the Agency's July 10, 2000 memorandum entitled *3,5-DCA (vinclozolin degradate): Drinking Water EECs from golf course and canola use* amending the surface water model simulations for 3,5-DCA, and the July 6, 2000 memorandum entitled *Vinclozolin: Drinking Water Levels of Concern Attributable to Vinclozolin Alone and Three Dicarboximide Fungicides Combined* amending the DWLOCs for 3,5-DCA.

Table 5. Drinking Water DWLOC and EEC Comparisons for Vinclozolin (plus B and E)

Population Subgroup	DWLOCs (ppb)[a]		EECs (ppb)		
	Acute	Chronic/ Cancer	Ground Water	Surface Water	
				Acute[b]	Chronic/Cancer[c]
U.S. General Population	N/A	41	0.57	11.6	9.4
Children (1-6 years)	N/A	11			
Females (13+)	Not feasible[d]	35			

[a] At 99.9th percentile of exposure

[b] Acute EEC represents the upper 1-in-10 year peak concentration.

[c] Chronic EEC represents the upper 1-in-10 year mean annual concentration.

[d] Risk from food alone currently exceeds the Agency's level of concern at the 99.9th percentile of exposure.

Table 6. Drinking Water DWLOC and EEC Comparisons for 3,5-DCA (cancer)[a]

Population Subgroup	DWLOC (ppb)	Chronic EECs (ppb)	
	Cancer	Surface Water	Ground Water
U.S. General Population	0.47	2.3	7.2

[a] See 2-4-00 memo entitled *Vinclozolin and Its Degradates* for an explanation of the method used to simulate 3,5-DCA concentrations.

Acute risk DWLOCs could not be calculated according to the current use pattern because the risk associated solely with food sources of acute dietary risk exceed the Agency's level of concern at the 99.9th percentile of exposure. However, if only drinking water is considered, i.e., if it is assumed that all of the water consumed per day contains vinclozolin residues at the peak surface water EEC level, the % aPAD consumed would be small relative to food exposure (females 13-50).

As stated in the dietary (food) risk assessment, given the level of refinement in the vinclozolin exposure estimate, EPA believes using the highest percentiles of exposure unreasonably overstates risk. Acute DWLOCs were therefore calculated for those percentiles of exposure resulting in apparent risks below 100% aPAD (the Agency's level of concern) in Table 7. At all but the very highest percentiles of exposure (99.85th and above), the DWLOC for vinclozolin is greater than the EEC of 11.6 ppb in surface water and 0.57 ppb in ground water. Upon completion of the phase-out in 2004, acute risk from food + drinking water will be below the Agency's level of concern at the 99.9th percentile of exposure. The peak EEC of 11.6 ppb will be below the future acute DWLOC of 170 ppb.

Table 7. Acute Dietary Exposure and Risk Estimates and DWLOCs for Vinclozolin at Various Percentiles of Exposure

Percentile of Exposure	Exposure (mg/kg/day)	%aPAD	DWLOC (ppb)
99.9	0.007196	120	N/A
99.85	0.005877	98	4
99.8	0.004987	83	30
99.75	0.004425	73	47
99.6	0.003316	60	80
99.5	0.002933	49	92
99.25	0.002295	40	111
99.1	0.002027	33	119
99.0	0.001857	31	124

For chronic (non-cancer and cancer) risk, comparisons between the DWLOC of 11 for the most sensitive subpopulation (children 1-6) and the highest chronic EEC (in surface water) of 9.4 ppb for vinclozolin indicates a lack of dietary chronic/overall antiandrogenic risk concern for drinking water sources of vinclozolin. No refinement of these drinking water estimates is needed.

For cancer risk from 3,5-DCA, both the surface water and ground water estimated concentrations (2.3 and 7.2 ppb respectively) exceed the DWLOC of 0.47 ppb indicating a potential for concern. Considerable degradation of vinclozolin and its metabolites to 3,5-DCA in the soil/water column is likely to occur over time. Therefore, it is a conservative yet conceivable assumption that the EEC levels could occur in drinking water.

The carcinogenic DWLOC for 3,5-DCA based on the commodities available for consumption *after* completion of the phase-out has been calculated to be 0.55 ppb. The surface and ground water EECs of 2.33 ppb and 7.2 ppb respectively, still exceed the DWLOC.

In evaluating whether the surface and ground water EECs indicate a risk of concern, the following factors must be considered:

1) The surface water assessment on turf is based on GENEEC, a screening-level Tier I model. At present, PRZM-EXAMS, the Tier II model, does not have the appropriate parameters to accurately model turf runoff. Although GENEEC is not an ideal tool for use in drinking water risk assessments, it can provide high-end estimates of the concentrations that might be found in a confined farm pond. Surface water source drinking water does not typically come from this type of scenario, but rather from bodies of water that are substantially larger than such ponds and from diverse watersheds. Unlike a confined pond, there is always some flow (in a river) or turn over (in a lake or reservoir) resulting in an over-estimation of the persistence of the chemicals near the drinking water utility intakes.

2) The GENEEC model uses the 56-day average of pesticide concentrations after an application of pesticide. This short time period may not adequately characterize a person's average daily exposure over a year, even more so, over a life time of seventy years.

3) The reported surface water EEC represents a value that might be exceeded once in every 10 years. For the other 9 out of 10 years, the level of residue in drinking water is likely to be below the EEC. Therefore, a person may be exposed to the estimated EEC once in every 10 years or a total of seven times during a lifetime of 70 years. The Agency believes that adverse effects from such a lifetime exposure is minimal.

4) The Agency does not believe that the SCIGROW values are representative of actual ground water concentrations. SCIGROW was developed by fitting an empirical model to the groundwater concentrations of 10 pesticides obtained from the Agency's small-scale prospective groundwater studies. Variables considered in the model include the K_{oc} and the soil half life of the pesticides. Since the K_{oc} and half life for 3,5-DCA (> 1,000 days) most likely fall outside of the range used in the development of the model, one can expect deviations from actual to predicted concentrations. Because of this uncertainty and because of the persistence and mobility of 3,5-DCA, a groundwater study targeted at 3,5-DCA in the vicinity of vinclozolin use on turf would provide useful information for assessing the potential of groundwater contamination.

In light of all these factors, EPA believes that it is likely that there is no risk of concern from exposure to vinclozolin-derived 3,5-DCA in surface or ground water. Nonetheless, the exceedance of the DWLOC, based on a screening level model, does indicate a need to take steps to insure that exposures do not present a risk concern.

3. Non-dietary Exposure and Risk to the General Population

There are no vinclozolin pesticide products registered for use by homeowners. Vinclozolin can, however, be occupationally used in a manner that may lead to post-application exposures to the general population. In particular, golfers playing on treated golf courses and homeowners and their families coming into contact with or playing on sod which has been previously treated on a sod farm can be exposed. Toddlers may experience dermal exposure to vinclozolin-treated sod as well as oral exposures in a variety of ways including inadvertent hand-to-mouth transfer of residues and ingestion of turfgrass or soil bearing residues. Golfers are exposed only through dermal contact. The inputs and results of this risk assessment are presented below.

a. Toxicity

The following table details the hazard aspects of the non dietary risk assessment for vinclozolin.

Table 8. Toxicity Endpoints Selected for the Non-occupational Assessment

Exposure Route/Duration	Subpopulation	Dose	Endpoint/Study
Short- and intermediate term dermal and inhalation	Females 13+	NOAEL: 3 mg/kg/day (used for golfers)	Decreased male prostate weight from pre-natal developmental toxicity study in rats MRID 44395701 & -02
Short- and intermediate term dermal, inhalation, and nondietary ingestion	Infants and children	NOAEL: 5 mg/kg/day (used for children playing on turf)	Decrease in number of days to preputial separation (a measure of puberty) from a post-natal developmental toxicity study in rats No MRID: Presentation by Dr. Earl Gray to SAP 10/96.

As the endpoints selected are from oral toxicity studies (NOAEL of 3 mg/kg/day for golfers and NOAEL of 5 mg/kg/day for children), a 25% dermal absorption factor (based on a rat dermal absorption study, MRID 41824309) and a 100% default inhalation absorption factor were applied. The 10X FQPA safety factor was retained, raising the Agency's level of concern (i.e. target MOE) to 1,000. No chronic exposures or exposures of sufficient duration to cause cancer were identified. All residential exposures were considered to be of a short- and /or intermediate-term duration (i.e. exposures can occur from 1 day to several months). The same endpoints apply to both durations of exposure. However, as noted above, there are different endpoints for children and adults respectively.

b. Exposure Assumptions

Exposure to children playing on turf from sod farms was calculated using the chemical and activity-specific transfer coefficients from a vinclozolin-specific Jazzercize study (MRID 43343702). Additionally, the turf transferable residue (TTR) concentrations that served as the basis for these calculations were chemical-specific and collected in California, Florida, and Pennsylvania (MRIDs 43343701 and 4352801). The transfer coefficient value was adjusted to account for the differences between adults and children and also to account for the activity levels that Jazzercize is intended to represent. Golfer exposures were calculated using a standard transfer coefficient for that activity and the same TTR data as with the children.

Mouthing behaviors in children can also contribute to overall exposure. The Agency considered these exposures by using the guidance in its SOPs for residential exposure assessments to calculate exposures from hand-to-mouth behavior, mouthing objects, and ingesting small quantities of sod. These exposures were added to the dermal dose levels to calculate the overall burden for children.

It was assumed that children were engaged in active play activities for 2 hours per day on turf. The Jazzercize transfer coefficient was adjusted as per the recent FIFRA SAP meeting where 20 minutes of Jazzercize represents 1 hour of heavy play for children. The exposure duration used for golfers was 4 hours; the approximate amount of time required to complete an 18 hole round of golf. Body weights of 15 and 60 kg have been used for toddler and adult risk calculations, respectively.

c. Non-occupational Risk

Post-application risks to the general population were considered for golfers following treatment of greens, tees, and fairways. The risk to adult golfers who play a round on a course is below the Agency's level of concern on the day of application (MOE = 1700). Given the magnitude of the MOE for adult golfers, the Agency does not believe that the risks to adolescent golfers would exceed the Agency level of concern because the skin surface area/body weight ratio of the typical child golfer who is 12 through adulthood is similar to that of adults (within 15%). For child golfers under the age of 12, the MOE is 1670. Therefore, the risk to golfers of all age ranges is below the Agency's level of concern.

The MOE for toddlers playing on sod which had been treated with vinclozolin on a sod farm is 33 on the day of application. This MOE represents an upper-bound exposure which includes non-dietary ingestion pathways (i.e. dermal exposure and oral exposures including hand to mouth, ingestion of soils and mouthing treated turf). Chemical-specific data show that turf transferable residues on sod decline such that risks fall beneath the Agency's level of concern 24 days after application (MOE = 1100). To mitigate the unacceptable risk resulting from exposure before the 24 day period has elapsed, the registrant has submitted label amendments deleting use on sod farms (except for transplant onto golf courses), and has begun the immediate restickering of all product in the channels of trade to require a

24 day period before sod can be harvested. It is assumed that, at a minimum, sod harvesting and replanting in a residential setting would take an additional two days; thereby, providing a total of 26 days for residues of vinclozolin to decline to an acceptable level. Although the Agency's level of concern would have been exceeded, the risk reduction measures implemented by the registrant, when taken into consideration with the conservative exposure scenario and exposure assumptions, immediately reduce risk such that it is below the Agency's level of concern.

4. Aggregate Risk

The vinclozolin aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water routes) and non-occupational exposure sources. Only the short- and intermediate-term aggregate risk assessment includes dermal/inhalation exposure from nonoccupational settings in addition to the dietary (food and water) exposure. Currently there are no registered residential uses for vinclozolin. BASF voluntarily removed all residential uses from labels in 1997.

Acute Aggregate Risk

The acute dietary (food only) risk does not exceed the Agency's level of concern at percentiles of exposure up to the 99.8th percentile. The population of concern, females (13+) utilized 83% of the dietary (food only) aPAD at the 99.8th percentile of exposure. For drinking water, the EEC of 11.6 ppb in surface water and the EEC of 0.57 ppb in groundwater did not exceed the DWLOC of 30 ppb at the 99.8th percentile of exposure. After completion of the phase-out, acute dietary risk from food will drop to 4% of the aPAD; and the acute DWLOC of 170 ppb greatly exceeds the highest EEC.

Chronic (Non-Cancer and Cancer) Aggregate Risk

Considering both the chronic (non-cancer and cancer) dietary (food) risk estimates and the surface and ground water estimated concentrations in drinking water for vinclozolin, risk is below the Agency's level of concern.

Short-term and Intermediate-term Aggregate Risk

Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus short- and intermediate-term dermal and oral exposure from non-occupational settings. Average food and water exposure values are used because food and water are intended to represent background levels of exposure. The risk currently exceeds the Agency's level of concern due to the residential component alone, toddler exposure to treated sod. In all aggregate risk scenarios, food and water sources contribute negligible risk at the 99.9th percentile of exposure when compared to the residential sod exposure contribution.

Short-term/intermediate-term aggregate risk was re-calculated for children considering the immediate restickering of all vinclozolin products for sod farm use to include a 24-day period before harvesting. When aggregating food, water and sod (assuming 100% consumption of drinking water containing vinclozolin at the maximum average EEC of 9.4 ppb) the sod pre-harvest interval (PHI) of 24 days still results in short- and intermediate-term aggregate risk below the Agency's level of concern. Food (at

the 99.9th percentile of food exposure), water (assuming 100% consumption of drinking water containing vinclozolin at the maximum average EEC), and adult/child golfer exposure do not exceed the Agency's level of concern when aggregated. The aggregation of child golfer exposure with food, water, and sod exposure sources is not appropriate due to the unlikelihood that the same child would be exposed to vinclozolin residues from both newly transplanted sod and golf course turf over a few days to a several-month interval.

Carcinogenic Aggregate Risk from 3,5-DCA

The Agency generally considers 1×10^{-6} (1 in 1 million) or less as negligible risk for cancer. The results of this analysis indicate that the cancer dietary (food) risk estimate of 2.6×10^{-7} associated with the uses supported through reregistration is not of concern. The DWLOC for 3,5-DCA originating from vinclozolin has been calculated to be 0.47 ppb for the general population; based on the commodities available for consumption after this use season, the carcinogenic DWLOC for 3,5-DCA has been calculated to be 0.55 ppb. Both the ground and surface water EECs exceed these DWLOCs indicating a potential for concern.

Multichemical Carcinogenic Aggregate Risk from 3,5-DCA

The Agency considered the relative contribution of vinclozolin, iprodione, and procymidone to the multichemical and multiroute/aggregated carcinogenic dietary risk resulting from exposure to 3,5-DCA which is a metabolite common (to some extent) to all three compounds. The Q_1^* used for the 3,5-DCA cancer risk assessments is that of p-chloroaniline, a direct-acting carcinogen inducing spleen sarcomas. There is an uncertainty in the risk estimate because a surrogate Q* is being used for 3,5-DCA; however, since p-chloroaniline is more reactive than 3,5-dichloroaniline, 3,5-DCA is believed to be less carcinogenic to some degree.

Vinclozolin. As summarized above, the dietary (food and wine only) cancer risk to the general population associated with 3,5-DCA derived from vinclozolin is estimated to be 2.6×10^{-7} including all currently registered uses. This cancer risk due to food sources of exposure alone is below the Agency's level of concern ($<1 \times 10^{-6}$). The DWLOC for 3,5-DCA originating from vinclozolin has been calculated to be 0.47 ppb for the general population; the EECs exceed the DWLOC indicating a potential for drinking water concern.

Iprodione. The risk associated with 3,5-DCA derived from iprodione was 5.85×10^{-7} from food and wine sources (7/31/98 RED). The DWLOC for 3,5-DCA derived from domestic uses of iprodione was estimated to be 0.53 ppb. The Agency has recently recalculated drinking water EECs from application to (golf course) turf, for which iprodione has a maximum annual application rate of 24 lbs. ai/acre/season. The EEC in surface water and ground water associated with the use of iprodione alone was estimated to be 18 ppb and 38 ppb respectively. These EECs exceed the DWLOC indicating a potential for drinking water concern.

Procymidone. There is no drinking water exposure because the tolerance for procymidone is for imported wine only. The 3,5-DCA metabolite was not detected in grapes, but occurs during fermentation. The cancer risk associated with 3,5-DCA in imported wine was estimated to be 4.8 x 10^{-7} (7/31/98 iprodione RED) which falls below the Agency's level of concern.

All Three Dicarboximide Fungicides. The cumulative, food-only cancer risk associated with 3,5-DCA derived from **all three** of these imide fungicides is 5.6 x 10^{-7}. This food-only risk is considered by the Agency to be negligible. The 3,5-DCA DWLOC from all three imide fungicides including those currently registered vinclozolin uses not being supported after this use season is 0.26 ppb. The vinclozolin- and iprodione-derived 3,5-DCA EECs exceed the aggregate carcinogenic DWLOC indicating a potential for concern.

5. Cumulative Risk

Vinclozolin is a member of the imide group of the dicarboximide class of fungicides, as are iprodione and procymidone. There is some evidence that these compounds induce similar toxic effects. Further, all of these fungicides appear to be antiandrogenic. The mechanistic basis for their antiandrogenic properties has been studied to varying degrees. There are studies underway at EPA's National Health and Environmental Effects Laboratory to better elucidate the mechanism of toxicity for these antiandrogenic fungicides as well as mixture studies on how they interact. Although all three of these fungicides effectively reduce the level of testosterone available in the cell, they do so by different pathways. Vinclozolin and procymidone bind and compete for the androgen receptor. Iprodione disrupts the endocrine system by inhibiting androgen synthesis rather than competing for the androgen receptor. It should be noted that these three chemicals do not have any known metabolites/degradates in common with the exception of 3,5-dichloroaniline which is structurally and toxicologically different from the parent compounds and unlikely to be antiandrogenic.

The androgen system may be modulated in different ways including competitive binding to androgen receptors, interference with gene control over the synthesis of several enzymes or other factors associated with synthesis of androgen and testosterone. All of these variables relate to the potency, specificity, and site of action of the antiandrogen and determine the expression of the antiandrogenicity induced by various compounds. Because of the complexity of the androgen system, a careful evaluation of all the available data is needed as well as peer review by the FIFRA Science Advisory Panel before a formal decision is made regarding whether or not these compounds share a common mechanism of toxicity. The evaluation of a common mechanism would follow the 1999 EPA Guidance for Identifying Pesticide Chemicals and Other Substances That Have A Common Mechanism of Toxicity (Fed. Reg. 64:5796-5799). Furthermore, procymidone has yet to be subjected to the reregistration/tolerance reassessment process and, as part of this process, its toxicology database must meet current standards of acceptability. In sum, although there are data suggesting that these dicarboximide fungicides induce some of the same antiandrogenic effects, the mechanism by which they cause these toxic effects has not been adequately evaluated.

Even after an evaluation of all the data and a decision is made regarding a common mechanism of toxicity, other analyses need to be conducted regarding the integration of exposure and hazard data to determine the likelihood that such groupings might result in a cumulative risk as described in the Agency's *Proposed Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity* (see http://www.epa.gov/scipoly/sap/1999/september/cumdoc.pdf). Only then can it be determined whether there is a need to conduct a cumulative risk assessment on these dicarboximide fungicides. Therefore, for this assessment of vinclozolin and its antiandrogenic metabolites, EPA will not conduct a cumulative risk assessment.

6. Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, applying a pesticide or re-entering treated sites. Dermal and inhalation risk for individuals performing these activities is measured by a Margin of Exposure (MOE), which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) from an animal study. For vinclozolin, MOEs greater than 100 are not of concern.

a. Toxicity

Vinclozolin has a low order of acute toxicity via dermal and inhalation routes, and produces slight irritation to the eyes and skin. Vinclozolin acts as a skin sensitizer. The following is the acute toxicity profile for vinclozolin:

Table 9. Acute Toxicity of Vinclozolin.

Route of Exposure	MRID No.	Results	Toxicity Category
Dermal	00086339	LD50 > 2500 mg/kg in both males and females.	III
Inhalation	00075474	LC50 > 29.1 mg/l.	IV
Eye Irritation	00086341	Slight eye irritation cleared by day 8.	III
Dermal Irritation	00086340	Slight skin irritation cleared within 72 hours.	IV
Dermal Sensitizer	00080451	Skin sensitizer in 4/9 animals.	Sensitizer

The toxicological endpoint used in the Occupational Risk Assessment for vinclozolin is listed in Table 10. Long-term dermal or inhalation occupational exposure are not expected to occur for the uses being supported by the registrant.

Table 10: Toxicity Endpoint for Vinclozolin Occupational Risk Assessment

Exposure Route/Duration	Dose	Endpoint/Study
Short- and intermediate-term dermal and inhalation	NOAEL: 3 mg/kg/day	Decreased male prostate weight from pre-natal developmental toxicity study in rats MRID 44395701 & -02

A dermal absorption factor of 25.2% was estimated based on the results of a dermal absorption study in rats (MRID 41824309). A default inhalation absorption factor of 100% has been assumed since route-to-route extrapolation is required. Based on the current use pattern and handler activities, long-term (chronic) exposure is not anticipated nor expected in food production; however, in very limited cases, exposures can occur over extended periods of time that are considered to be chronic in nature (i.e., 180 working days or more per year) or of sufficient duration for the development of cancer. These exposures are only thought to occur in the ornamental/floriculture industry. The registrant has already submitted label amendments to delete use on ornamentals. Consequently, chronic and cancer endpoints and risk calculations are no longer appropriate as they are based on a lifetime (70 years) of exposure.

b. Handler Exposure Data Sources and Assumptions

The Agency has identified the major exposure scenarios for which there is potential for occupational handler exposure during mixing, loading and applying products containing vinclozolin. The majority of analyses were performed using the *Pesticide Handlers Exposure Database* (PHED), Version 1.1. PHED is a comprehensive generic/surrogate exposure database containing a large number of measured values of dermal and inhalation exposures for pesticide workers involved in handling pesticides. Two vinclozolin handler exposure studies have been reviewed and the results from the chemical-specific studies have been added to the PHED data to calculate unit exposure values. By combining the chemical-specific data with PHED, the Agency was able to increase the sample size and number of studies. This allows the Agency to better characterize the variety of equipment used throughout the country and accounts for the large variability of exposures among handlers.

The exposure factors (e.g., body weight, amount treated per day, protection factors, etc.) are all standard values used by the Agency. Anticipated use patterns, application methods, and range of application rates were derived from current labeling. Since the selected endpoint is from a developmental study, the appropriate population sub-group is female workers and the 60 kg default Agency female body weight was used.

Occupational handler exposure assessments are conducted by the Agency using increasing levels of personal protection. The Agency typically evaluates all exposure scenarios with minimal protection and then adds additional protective measures using a tiered approach (going from minimal to maximum levels of protection) to obtain an MOE equal or greater than the target MOE, which is typically 100. The lowest tier is represented by the baseline exposure scenario (i.e., single layer clothing, socks, and shoes), followed by, if MOEs are less than 100, increasing levels of risk mitigation, i.e., personal protective equipment (PPE) and engineering controls. Engineering controls include such measures as an enclosed cab tractor for application scenarios, a closed mixing/loading system for liquids or a packaged based system (e.g., Lock N Load for granulars or water soluble packaging for wettable powders). Some engineering controls are not feasible for certain scenarios (e.g., for handheld application methods there are no known devices that can be used to routinely lower the exposures).

The levels of protection are outlined in Table 11. For more information on the assumptions and calculations of potential risks to workers, see the *Occupational Exposure* section of the May 12, 2000 Human Health Risk Assessment and the Agency memo entitled, *The Revised Occupational and Residential Exposure Aspects of the HED Chapter of the Reregistration Eligibility Decision Document for Vinclozolin.*

Vinclozolin can be applied using a wide array of application equipment. In agriculture, groundboom, aerial, and airblast applications can be made typically at a single event rate of 0.5 to 1 pound active ingredient/acre depending on crop. Other applications are completed using handheld equipment such as low pressure handwand sprayers, backpack sprayers, low pressure/high volume turfguns, fogging machines in greenhouses, and dipping tanks.

Vinclozolin is formulated as a 50% extruded granule (EG) sold only in water-soluble packets and as a 50% dry flowable (DF) formulation for open pour. DF and EG are dissolved in water and sprayed as a liquid. In 1998, BASF requested voluntary cancellation of the 41% liquid flowable (FL) product and the wettable powder (WP) product (7969-53). Although a minimal amount of these formulated products may still exist in the channels of trade, they have not been considered.

PPE on Current Labels

All labels require that handlers wear coveralls over long-sleeved shirt and long pants, chemical resistant gloves, chemical-resistant footwear plus socks, protective eyewear, chemical resistant headgear for overhead exposure, a chemical resistant apron when mixing, loading, or cleaning equipment, an organic vapor-removing cartridge in enclosed areas and a dust/mist respirator for outdoor exposures.

Epidemiology

Based on reports from the OPP Incident Data System; Poison Control Centers; California Department of Pesticide Regulation; and the National Pesticide Telecommunications Network, there were relatively few incidents of illness due to vinclozolin exposure. However, the Agency does not have significant concerns for acute poisoning, which is the most likely to be reported, but rather the risks associated with developmental effects.

c. Handler Risk Summary

For *short- and intermediate-term risk*, many exposure scenarios do not exceed the Agency's level of concern at the baseline level of personal protection. In some cases, more protection is required such as additional PPE or engineering controls. A description of the occupational mixer/loader/applicator short- and intermediate-term scenarios and resulting risks are summarized in Table 14. Chronic exposures were only assessed for certain tasks associated with the production of ornamentals in a greenhouse. Due to the voluntary cancellation on ornamentals, these chronic and cancer risk estimates are not presented, but *chronic/cancer risk* to handlers was below the Agency's level of concern at the currently required level of PPE with the exception of treating cut flowers with a backpack sprayer.

Table 11. Mixer/Loader/Applicator Short- and Intermediate-term Risk Summary for Combinations of Dermal and Inhalation Protective Measures

Scen. no.[a]	Scen. descriptor	Crop type	Rate	Acres or gallons	Baseline	Single layer, gloves & no respirator	Single layer, gloves & dust/mist respirator	Double layer, gloves and no respirator	Double layer, gloves, and dust/mist respirator	Eng. controls
OCCUPATIONAL MIXER/LOADERS										
1a	M/L dry flowables for aerial & chemigation	Canola (typical rate)	0.4	350	74	74	77	102		
		Lettuce & Onions	1	350	30	30	31	41	43	1501
		Ornamentals	1.3	350	23	23	24	31	33	1155
1b	M/L dry flowables for airblast	Raspberries	0.5	40	517					
		Raspberries & Kiwi	1	40	259					
		Ornamentals	1.3	40	199					
1c	M/L dry flowables for groundboom	Canola (typical rate)	0.4	80	323					
		Lettuce & Onions	1	80	129					
		Ornamentals	1.3	80	99	99	103			
1d	M/L dry flowables for high pressure handwand	Ornamentals	0.0025	1000	4137					
		Ornamentals	0.005	100	2069					
1 e	M/L dry flowables for dipping	Cut Flowers & Others	0.015	100	6896					
		Chicory/Endive Forcing Tray	1	500	21	21	21	29	30	1051
1f	M/L dry flowables for thermal fogging[b]	Ornamentals	Not specified	Not specified						

Scen. no.[a]	Scen. descriptor	Crop type	Rate	Acres or gallons	Baseline	Single layer, gloves & no respirator	Single layer, gloves & dust/mist respirator	Double layer, gloves and no respirator	Double layer, gloves, and dust/mist respirator	Eng. controls
1g	M/L dry flowables for low pressure/high volume turfgun	Turf	1.35	5	1532					
3a	M/L extruded granules for aerial & chemigation	Canola (typical rate)	0.4	350	337					
		Lettuce & Onions	1	350	135					
		Ornamentals	1.3	350	104	115				
3b	M/L extruded granules for airblast	Raspberries	0.5	40	2358					
		Raspberries	1	40	1179					
		Ornamentals	1.3	40	907					
3c	M/L extruded granules for groundboom	Canola (typical rate)	0.4	80	1474					
		Lettuce & Onions	1	80	589					
		Ornamentals	1.3	80	453					
3d	M/L extruded granules for high pressure handwand	Ornamentals	0.0025	1000	18864					
		Ornamentals	0.005	1000	9432					
3 e	M/L extruded granules for dipping	Cut Flowers & Others	0.015	100	31440					
3f	M/L extruded granules for thermal fogging[b]	Ornamentals	Not specified	Not specified						

Scen. no.[a]	Scen. descriptor	Crop type	Rate	Acres or gallons	Baseline	Single layer, gloves & no respirator	Single layer, gloves & dust/mist respirator	Double layer, gloves and no respirator	Double layer, gloves, and dust/mist respirator	Eng. controls
3g	M/L extruded granules for low pressure/high volume turfgun	Turf	1.35	5	6987					
OCCUPATIONAL APPLICATORS										
4	Applying Sprays With an Airblast Sprayer	Raspberries	0.5	40	95	139				
		Raspberries	1	40	47	69	73	75	80	859
		Ornamentals	1.3	40	36	53	56	58	61	661
5	Applying Sprays With a Groundboom Sprayer	Canola (typical rate)	0.4	80	1318					
		Lettuce & Onions	1	80	527					
		Ornamentals	1.3	80	406					
6	Aerial Application of Sprays With a Fixed Wing Aircraft	Canola (typical rate)	0.4	350	Not feasible	NF	NF	NF	NF	968
		Lettuce & Onions	1	350	Not feasible	NF	NF	NF	NF	387
		Ornamentals	1.3	350	Not feasible	NF	NF	NF	NF	298
7	Application by Thermal Fogging in Greenhouses[b]	Ornamentals	Not specified	Not specified						
8	Application by Dipping Cut Flowers & Nurserystock	Cut Flowers & Others	0.015	100	No data	ND	ND	ND	ND	NF
9	Application to Chicory/Endive in Forcing Trays	Chicory/Endive Forcing Tray	1	500	No data	ND	ND	ND	ND	NF
10	Applying With a High Pressure Handwand	Ornamentals	0.0025	1000	135					
		Ornamentals	0.005	1000	68	150				

Scen. no.[a]	Scen. descriptor	Crop type	Rate	Acres or gallons	Baseline	Single layer, gloves & no respirator	Single layer, gloves & dust/mist respirator	Double layer, gloves and no respirator	Double layer, gloves, and dust/mist respirator	Eng. controls
11	Application With a Low Pressure/High Volume Turfgun	Turf	1.35	5	136					
OCCUPATIONAL MIXER/LOADER/APPLICATORS										
12	Mixing/loading/ applying Liquids With a Low Pressure Handwand	Ornamentals	0.0025	40	71	13010				
		Ornamentals	0.005	40	36	6505				
		Cut Flower Spray	0.015	40	12	2168				
13	Mixing/loading/ applying Liquids With a Backpack Sprayer	Ornamentals	0.0025	40	No data	2727				
		Ornamentals	0.005	40	No data	1364				
		Cut Flower Spray	0.015	40	No data	455				
OCCUPATIONAL FLAGGERS										
14	Flagging For Aerial Spray Applications	Canola (typical rate)	0.4	350	412					
		Lettuce & Onions	1	350	165					
		Ornamentals	1.3	350	127					

[a] Scenario 2, which considered risk to mixers/loaders from the flowable formulation, has been removed from the table. This formulation is no longer manufactured and the registration will be canceled.

[b] Thermal fogging application rate unclear on labels.

d. Postapplication Risk Assessment

For workers entering a treated site, restricted entry intervals (REIs) are generally calculated to determine the minimum length of time required before workers are allowed to enter after treatment. The restricted-entry interval is established, in general, based upon the number of days following application that must elapse before the MOE for occupational exposure exceeds 100. The current REI on the labels for ornamentals, turf, lettuce, raspberries, and lettuce is 12 hours. The REI is 10 days for snap beans and 9 days for canola. The 24(c) label for kiwi states, "Do not reenter treated area until pesticide spray has dried, the waiting period for drying to occur need not exceed 24 hours".

e. Postapplication Data Sources and Assumptions

The post-application assessment was developed using chemical-specific dislodgeable foliar residue (DFR) data for peaches, strawberries, and turf. Exposure data using the Jazzercize method were also generated on turf. No chemical-specific residue dissipation data were available for any currently labeled crop except turf. Therefore, peach data were used to assess kiwi (an airblast study) while strawberry data (groundboom study) were used to complete the assessment for all other crops and ornamentals. This extrapolation was made based on similar application methods. The Agency has determined that it is more appropriate to extrapolate using vinclozolin-specific dissipation data for other currently labeled crops than it is to use the generic dissipation model.

Surrogate dermal transfer coefficients were used except on turf. Vinclozolin-specific transfer coefficients were available for peach and strawberry harvesting but were not used since these uses have been removed from labels and the activities and circumstances of the studies are distinct enough to not justify using them to quantitatively complete an assessment for other types of exposures associated with vinclozolin use. However, the available vinclozolin-specific transfer coefficients are within the same range as the Agency's standard values. The predominant exposure pathway is dermal. Inhalation exposure is not assessed because it is expected to be negligible once sprays have settled. 8 hours is the assumed standard workday, with the exception of 4 hours for golf course turf maintenance.

Changes to the Post-application Risk Assessment

BASF has recently submitted statistical information for use in evaluating the dislodgable foliar residue and turf transferable residue levels. The major difference between the two approaches was the manner in which the dissipation kinetics were handled; the Agency used a pseudo-first order approach and BASF used a curve fitting approach. EPA has accepted BASF's statistical analysis. The BASF calculated values generally result in somewhat lower DFR and TTR levels and associated risks than those presented in the May 12, 2000 Revised Human Health Risk Assessment. BASF's analysis of the data was used in postapplication risk calculations.

On August 7, 2000, the Agency adopted many new transfer coefficients based on data submitted by the Agricultural Reentry Task Force to replace default transfer coefficients and consequently has revised the post-application risk estimates for vinclozolin. The revision to the policy entails linking worker activities to

more specific crop/agronomic groupings and making better use of the available occupational post-application exposure data. Raspberries, ornamentals and onions have not been reevaluated because the registrant does not intend to support these uses. Note that revisions to the transfer coefficient policy only impact workers and do not effect the residential/non-occupational risk assessments. The same dislodgeable foliar or turf transferable residue data were used as in the previous risk assessment.

f. Short-/intermediate-term Post Application Risk

REIs are calculated in hours or days. Lettuce, kiwi and turf pose a risk concern, i.e., the Agency does not believe that the currently labeled REI is of sufficient duration to protect workers from exposure to residues of concern. Post-application risks based on the curve fitting approach and the revised transfer coefficient policy are presented for lettuce, kiwi, snap beans, canola and turf in Table 12. Onions, raspberries and ornamentals have **not** been updated by the revised policy and have not been included.

The pre-harvest interval (PHI) for each crop is also presented in Table 12. The PHI is designed to make sure that treated crops will have residues below tolerance level when marketed. PHIs are based on residues in the edible portion of the treated plant, whereas REIs are based on residues available on the surfaces of foliage of the treated plant that is transferable to a worker.

Table 12. REIs at which MOE exceeds 100

Commodity	PHI (days)	Activity	Day at which MOE exceeds 100 (REI)
Lettuce	28	Scouting, irrigation, thinning and weeding of immature lettuce	1
		Scouting and irrigation of mature lettuce	7
		Hand harvesting	11
Kiwi	7	Scouting	1
		Hand harvesting, thinning, pruning	6
Low-growing snap beans	10	Scouting, irrigation, thinning, and weeding of immature snap beans	12 hours
		Scouting, irrigating, thinning and weeding mature snap beans	7
		Hand harvesting*	11
Trellised snap beans	10	Irrigation, scouting, and hand weeding immature plants	12 hours
		Scouting, training and tying mature plants	1
		Hand harvesting, thinning and pruning	6
Canola	N/A	Scouting, irrigating, thinning and weeding of immature plants	12 hours
		Scouting, irrigating, thinning and weeding mature plants	7
Turf	N/A	Aerating, fertilizing, and mowing	12 hours
		Transplanting, hand weeding and hand/mechanical harvest*	5

* Hand harvesting is not of concern because current labels specify mechanical harvesting only

IV. Chronic/Cancer Post Application Risk

Occupational chronic/cancer risks were only assessed for certain tasks associated with the production of ornamentals in a greenhouse. For ornamentals, risk estimates have not been presented and risk management is not considered necessary due to the registrant's request for voluntary cancellation. It must be noted that the Agency had concerns for the use of vinclozolin on ornamentals based on occupational postapplication exposures. Chronic risks did not typically fall to an acceptable level until 30 to 40 days after application. Population-based cancer risks still exceeded the Agency's level of concern even 50 days after application for all activities considered including sorting/packing, irrigation, and cutting flowers. The length of these reentry restrictions are not considered feasible.

A. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see the Environmental Fate and Effects Division chapter, dated June 6, 1996 and the memo entitled, *Errata for Terrestrial Assessment of Revised Uses*, dated December 15, 1999.

1. Environmental Fate and Transport Degradation

Acceptable and supplemental laboratory and field data indicate that parent vinclozolin is relatively labile and dissipates in the environment by microbial-mediated hydrolysis, soil metabolism, abiotic degradation, and transport with water. Metabolite B is a common degradate of hydrolysis, soil metabolism, and photolysis. The other principal degradation products of vinclozolin are 3,5-dichloroaniline and metabolite E, which appears to be a degradation product of parent and metabolite B. Other degradates are formed in smaller concentrations. Metabolite E degrades to 3,5-dichloroaniline, which appears to resist further degradation.

Mobility

Vinclozolin and its principal degradates are potentially very mobile to slightly mobile in soil. Metabolites B, E and 3,5-DCA are potentially very mobile to slightly mobile and may be transported with water through the soil profile or with surface runoff. Studies suggest that 3,5-DCA, metabolite B and metabolite E are of similar mobility. Studies also suggest that B and E are much less persistent than 3,5-DCA. Experimental evidence has shown 3,5-DCA to be resistant to degradation processes. Since 3,5-DCA is likely much more persistent and of similar or greater mobility than the intermediates B and E, the concentrations of these individual degradates should be lower than for 3,5-DCA (on a mole concentration basis). Residues are likely to be most mobile in sandy soils low in organic matter.

Field Dissipation

In acceptable terrestrial field dissipation studies conducted in FL, NY, MO, and CA, vinclozolin dissipated with half-lives of 34 to 94 days. Half-lives for total residues (vinclozolin plus its dichloroaniline-containing metabolites) were 179 to >1000 days. Persistence of total residues appeared to be attributable to the resistance of 3,5-DCA to degradation and to the inclusion of soil-bound residues in the data. Intermittent detections of residues were reported at soil depths of 12-18, 18-24, and 24-30 inches. 3,5-DCA was detected regularly deeper than 6 inches. Residues may accumulate and be available for rotational crop uptake.

Because degradates of vinclozolin are mobile and can be persistent under certain environmental conditions, the chemical has the potential to contaminate ground water. Vinclozolin can be transported to surface water at application via spray drift from aerial and ground applications. Also, vinclozolin and its degradation products could be available for runoff for several weeks to months post-application. Vinclozolin has a low potential to bioaccumulate in fish.

2. Ecological Toxicity

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations based on environmental fate characteristics, pesticide use, and/or monitoring data. To evaluate the potential risk to nontarget organisms from the use of vinclozolin products, EPA calculates a Risk Quotient (RQ), which is the ratio of the estimated exposure concentration to the toxicity endpoint values, such as the LC50 (the median concentration of a substance which causes death to 50% of the test animals). The RQ is simply a means of integrating the results of ecological exposure and ecological toxicity. These RQ values are compared to levels of concern (LOCs), which provide an indication of the relative risk the particular pesticide and/or use may pose for nontarget organisms. If the RQ does not exceed the LOC, it is unlikely that the pesticide will pose a significant risk. Similarly, when RQs are equal to or greater than the LOC, additional refinements or mitigation may be necessary. Use, toxicity, fate, and exposure are considered to characterize the risk as well as the level of certainty and uncertainty in the assessment. EPA further characterizes ecological risk based on any reported aquatic or terrestrial incidents to nontarget organisms in the field (e.g., fish or bird kills). Refer to the Ecological Effects and Fate Chapter for the Vinclozolin RED for additional information.

Results indicate that vinclozolin is practically nontoxic to birds, mammals, and honey bees on an acute basis. Vinclozolin is moderately toxic to freshwater/estuarine fish and freshwater/estuarine invertebrates on an acute basis. In general, the Agency has concerns in relation to chronic adverse reproductive effects to mammalian and avian species resulting from exposure to vinclozolin. Vinclozolin and/or its metabolites have been shown *in vitro* and *in vivo* to be potent mammalian anti-androgenic compounds, inhibiting androgen receptor binding and gene expression. In addition to the adverse effects observed in the male fetuses in the mammalian species, testicular effects have also been reported in the avian species. The chronic risks presented in this document are based on "typical" application rates.

Risks to Birds

Acute risk quotient calculations do not exceed levels of concern for a single application. The chronic LOC is exceeded for most food items. Raspberry use poses the greatest risk, with turfgrass/ornamental use next, then onions and lettuce, then snap beans and finally, the canola use exhibiting the least risk. It should be noted that after completion of the phase-out, application to turfgrass will be the only use site of concern.

The implication of environmental hormone disruption, coupled with avian chronic LOC exceedences based on conventional avian reproduction tests, suggests a risk concern for birds.

Risks to Mammals

Endpoints were based on endocrine disruption effects such as reduction of ano-genital distance and genital and reproductive tract malformations. Acute risk quotients do not exceed mammalian acute risk LOC's. In the mammalian chronic risk assessment, an assessment using average Kenega values and a 7-day foliar dissipation half-life resulted in low risk to mammals, i.e. all RQs were less than the LOC.

Risks to Insects

The data indicate that vinclozolin may be characterized as practically nontoxic to honey bees with an LD_{50} value of > 100 ug/bee. Therefore, vinclozolin does not pose a high risk to honey bees.

Risk to Aquatic Species

No estuarine, marine, or freshwater fish or invertebrate acute LOC was exceeded for the modeled use patterns. However, chronic risk to aquatic organisms has not been assessed due to lack of data. Chronic data are important for vinclozolin, which can be applied repeatedly during the growing season to most crops. In addition, reproductive impairment has been seen in birds and mammals on a chronic basis. The registrant is submitting all outstanding chronic data including a life cycle/life stage freshwater fish study and an aquatic invertebrate life cycle study.

Toxicity to Plants

Currently, aquatic plant testing is required for any fungicides that have outdoor non-residential terrestrial uses that may result in movement off-site due to drift. A ≥ 50% adverse effect to plants was not observed in the Tier I toxicity testing. However, plants were tested only up to 1 ppm (nominal concentration). The need for this study to be repeated at a test concentration of 2.6 ppm (the solubility level of vinclozolin) is relatively low because vinclozolin does not appear to adversely effect aquatic plants substantially at nominal test concentrations of 1.0 ppm.

Endangered Species

As there are chronic risks to non-target birds, endangered birds are likely be at even greater risk due to such factors as loss of habitat and smaller population sizes, which increase vulnerability. If endangered birds associated with the use sites treated with vinclozolin are likely to be exposed for a duration of time, a consultation with the US Fish and Wildlife Service may be needed. The need for the consultation would be based on the persistence and endocrine effects of the chemical as measured by the chronic effects data.

Incident Reports

The Agency is not aware of any incidents of wildlife mortality, however, there have been some reports of possible phytotoxicity to lawns and crops.

V. Risk Management, Reregistration and Tolerance Reassessment

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing vinclozolin as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing vinclozolin. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of vinclozolin. The Agency finds that all products[5] containing vinclozolin as the active ingredient are eligible for reregistration, provided the labeling and use changes specified in this document are made by the registrant. Actions needed to reregister particular products are addressed in Section V of this document.

EPA has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the active ingredient vinclozolin, as well as a vinclozolin-specific dietary risk assessment. The dietary risk assessment has not considered the possible cumulative effects of the dicarboximide fungicides as a class, nor all antiandrogenic pesticides as a whole, because the Agency has not yet made a decision regarding common mechanism of toxicity for antiandrogenic pesticides and has not determined the likelihood that such groupings might result in a cumulative risk assessment. Although EPA has not made this determination, the Agency is issuing this assessment now in order to identify risk reduction measures that are necessary to allow the continued use of vinclozolin. After a decision is made

[5]Under BASF's use cancellation proposal, the product Vorlan® (sold under EPA registration number 7969-85) would no longer be available since the product is for use on ornamentals only. This use site is not being supported by the registrant.

regarding common mechanism of toxicity, and the Agency has determined whether it is necessary to conduct a cumulative assessment, the Agency will address any outstanding risk concerns.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient in this case, the Agency has sufficient information on the health effects and on the environmental fate and effects of vinclozolin. The Agency has determined that vinclozolin products, if labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Under the Food Quality Protection Act, the Agency has determined that there is reasonable certainty that no harm will result to infants and children or the general population for aggregate exposure to vinclozolin. Therefore, the Agency concludes that all products containing vinclozolin are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has accepted the registrant's request to remove raspberries, onions and ornamentals from product registrations and proposed them in the Federal Register (65 FR 56894, FRL-6744-2). The Agency also proposed cancellation on kiwi and chicory in 2001, and lettuce and succulent beans in 2004. Finally, the Agency intends to propose to revoke the established import tolerances for peppers and cucumbers on January 1, 2001. These actions are based on BASF's request to change the vinclozolin registrations after discussions with the Agency.

In addition to these actions, the Agency has determined that use on turf is eligible for reregistration subject to the following conditions: To protect children from non-dietary exposure to treated turf, direct application to turf must only be permitted on golf courses and industrial parks. The "commercial" use pattern must be deleted which includes lawn and landscape areas at business and office complex sites and turf at professional sports complexes or arenas. Also, treated sod farm turf can only be produced for transplant onto golf course establishments.

The Agency may take other appropriate regulatory action if new information comes to the Agency's attention regarding vinclozolin. EPA may also require the submission of additional data (1) to support the registration of products containing vinclozolin, (2) if the data requirements for registration change, or (3) if the guidelines for generating such data change.

B. Summary of Public Participation Process

In 1998, EPA implemented a "pilot public participation process" for all organophosphate chemicals (OPs) undergoing the reregistration and tolerance reassessment process to provide opportunity for public involvement and stakeholder participation. The process currently involves at least three opportunities for formal external participation and comment, and establishes an official Agency docket for the entire process.

The Agency is now working towards establishing a similar process for all pesticides undergoing reevaluation. An abbreviated public participation process was employed for non-OP tolerance reassessment and reregistration activities scheduled in the year 2000. During Phase I of the interim process, the preliminary risk assessments are sent to the registrants, USDA, and other federal counterparts as appropriate, for error identification. Phase II begins at the close of Phase I's 30-day comment period. OPP has up to 30 days to consider comments submitted by the registrant, make revisions to the risk assessments, and to open the public docket. The opening of the docket initiates Phase III during which the public is given an opportunity to view the risk assessment documents and participate in the development of risk management. A notice was published in the Federal Register on August 18, 2000, announcing the availability of the vinclozolin risk assessments. While there was no formal public comment period, EPA accepted comments on the risk assessment documents. No comments have been received as of the approval date of this RED. Phase IV commences when a Federal Register Notice is published announcing the availability of the RED in the Public Docket and on the Internet. There will be a formal public comment period on the vinclozolin RED.

C. Regulatory Position

1. Determination of Safety for U.S. Population

EPA has determined that the established tolerances for vinclozolin, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, that there is a reasonable certainty of no harm for the general population. In reaching this determination, EPA has considered all available information on the toxicity, use practices and scenarios, and the environmental behavior of vinclozolin, as well as the possibility of cumulative effects from vinclozolin-derived 3,5-DCA residues and other chemicals which can metabolize to 3,5-DCA. The following is a characterization of the risks shown to be potentially of concern in the human health risk assessment for vinclozolin.

Acute Dietary (food and drinking water). Risks at the 99.9th percentile of exposure are typically used to assess risk when the exposure figures are highly refined. In this case, the exposure assessment is considered to be only somewhat refined and using the highest percentiles of exposure is believed to unreasonably overstate risk. For food, at all but the very highest percentiles of exposure (99.85th and above), the %aPAD is below 100%. When raspberries and onions are removed (BASF has already submitted label amendments to delete these uses), 98% of the aPAD is utilized. After completion of the registrant's phase-out plan, acute dietary risk from food is well below the Agency's level of concern for females 13+ with 4% of the aPAD consumed at the 99.9th percentile of exposure. Acute DWLOCs were also calculated at percentiles of food exposure less than 99.9. At all percentiles of exposure 99.8 and lower, the DWLOC exceeds the surface water EECs. EPA is reasonably certain that exposure to vinclozolin in food and drinking water will result in no harm.

Cancer Dietary (3,5-DCA in food and drinking water). A drinking water assessment for vinclozolin was conducted on its degradates assuming total breakdown to 3,5-DCA. This assumption is considered to be conservative but not unreasonable because 3,5-DCA is the terminal residue in soil/water and is persistent. Although monitoring data from surface and ground water sources are available on parent vinclozolin, none are available on the metabolites, therefore, screening level models were used. Surface and ground water exposure estimates based on application to turf exceed the DWLOC. In evaluating whether the estimated concentrations indicate a risk concern, EPA considered many factors and believes the GENEEC model may not accurately represent surface water concentrations of 3,5-DCA expected in drinking water at the point of consumption. These screening models are best used to determine that a chemical poses little or no exposure. If a risk assessment performed using a high-end/upper-bound exposure modeled by GENEEC does not exceed EPA's level of concern, there would be no reason to refine the assessment. In this case, estimates are of concern and surface water and ground water monitoring studies are needed. If the results of the study indicate that there is a concern with concentrations of vinclozolin-derived 3,5-DCA, risk mitigation steps may be necessary.

Multichemical Carcinogenic Aggregate Risk from 3,5-DCA. The cumulative, food-only cancer risk associated with 3,5-DCA derived from **all three** of these imide fungicides is 5.6×10^{-7}. This food-only risk is considered by the Agency to be negligible. The 3,5-DCA DWLOC from all three Imide fungicides including those currently registered vinclozolin uses not being supported after this use season is 0.26 ppb. The vinclozolin- and iprodione-derived 3,5-DCA EECs exceed the aggregate carcinogenic DWLOC indicating a potential for concern. Because the modeled estimates are derived from screening level models (GENEEC and SCI-GROW), they most likely do not accurately represent what may be found in drinking water. Water monitoring data will be required for both vinclozolin and iprodione as confirmation.

Non-dietary Exposure (children's exposure to treated turf) and Short-/Intermediate-term Aggregate Risk. The multiroute MOE for toddlers playing on sodfarm turf (which represents an upper-bound exposure including dermal, inhalation, and nondietary ingestion pathways) is 33 on the day of application (target MOE = 1,000). Residues on sod decline such that risks do not fall beneath the Agency's level of concern until 24 days after application (MOE = 1096). To mitigate the unacceptable risk resulting from exposure before the 24 day period has elapsed, the registrant has submitted label amendments to delete use on sod farms except for transfer onto golf course establishments and has restickered all products in the channels of trade to require a 24 day period before sod can be harvested. Although the Agency's level of concern would have been exceeded if the registrant had not agreed to such use limitations, EPA believes that these risk reduction measures, when taken into consideration with the extremely conservative exposure scenario and exposure assumptions, immediately reduce the exposure such that it is below the Agency's level of concern. In terms of aggregate short-/intermediate-term risk which also includes the contribution of food and drinking water, the 24-day sod PHI protects toddlers, the only population of concern.

3. Determination of Safety for Infants and Children

EPA has determined that the established tolerances for vinclozolin, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C)

of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of vinclozolin residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from vinclozolin residues, EPA considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. For vinclozolin, the FQPA safety factor of 10 was **retained** because: (1) there is evidence of increased susceptibility to offspring following *in utero* exposure to vinclozolin in the prenatal developmental toxicity study in rats; and (2) a developmental neurotoxicity study in rats with an expanded protocol is required for vinclozolin due to concern for the antiandrogenic properties of vinclozolin and its metabolites.

3. Endocrine Disruptor Effects

The Food Quality Protection Act requires that EPA develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific bases for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations.

Vinclozolin and some of its metabolites are already known to interfere with the endocrine system, exerting their effects most dramatically during the developmental stages of animals, resulting in reproductive effects in lab animals. All androgen dependent functions are reduced; the more sensitive organs and functions are the male sex organ weight reductions, reduced fertility and abnormal or ambiguous sexual differentiation in the male rat. Since the androgen receptor is widely conserved across species lines, anti-androgenic effects would be expected in humans. There is also evidence in the published literature that vinclozolin may affect the development and function of the neuroendocrine system. Vinclozolin and/or its metabolites also cause Leydig cell (testicular) tumors in rats which is probably related to the antiandrogenic activity of vinclozolin.

EPA has responded, in part, to vinclozolin's known endocrine disrupting capability by retaining the 10X FQPA Safety Factor, regulating on endpoints based on endocrine disruptor effects, and by requesting a developmental neurotoxicity study. Thus, despite the scientific uncertainty concerning the potential endocrine disrupting effects of vinclozolin, the Agency's actions incorporate meaningful aspects of our knowledge on the toxicological hazards of vinclozolin.

4. Cumulative Risks

The Food Quality Protection Act requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Vinclozolin, procymidone, and iprodione are members of the imide group of the dicarboximide class of fungicides which appear to be antiandrogenic. The androgen system may be modulated in different ways including competitive binding to androgen receptors, interference with gene control over the synthesis of several enzymes or other factors associated with synthesis of androgen and testosterone. All of these variables relate to the potency, specificity, and site of action of the antiandrogen and determine the expression of the antiandrogenicity induced by various compounds. Because of the complexity of the androgen system, a careful evaluation is still needed before a formal decision is made regarding whether or not these compounds modulate androgens by a common mechanism of toxicity. In addition, there may be other compounds outside of this class of fungicides that may also be considered antiandrogenic.

Similarly, the Agency is examining whether and to what extent some or all pesticides that may be carcinogens may also share a common mechanism of toxicity. Current information on the common mechanism of toxicity for possible or probable carcinogens is limited, and the Agency's understanding of this relationship needs to be further developed. As a result, the Agency has not determined if it would be appropriate to include them in a cumulative risk assessment with other carcinogenic chemicals.

At this time, the Agency does not believe it has sufficient reliable information concerning common mechanism issues to conclude that vinclozolin shares a common mechanism of toxicity with the other dicarboximide fungicides, possible antiandrogens, or possible human carcinogen chemicals. Therefore, for the purposes of this risk assessment, the Agency has assumed that vinclozolin does not share a common mechanism of toxicity with other chemicals. After a decision is made regarding common mechanism of toxicity, and if the Agency has determined that a cumulative assessment is necessary, the Agency will address any outstanding risk concerns at that time.

D. Tolerance Summary

The established tolerances [40 CFR §180.380] for residues of vinclozolin in/on plant commodities are currently expressed in terms of vinclozolin (3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione) and its metabolites containing the 3,5-dichloroaniline moiety in or on the food commodities. Following evaluation of plant metabolism studies, the Agency has affirmed that the vinclozolin residues that warrant regulation in plant commodities are those that are currently regulated. Sufficient data have been submitted to reassess the established tolerances for the following plant commodities, as defined: succulent beans, Belgian endive (tops), cucumbers, wine grapes, kiwifruit, head and leaf lettuce, dry bulb onions, bell peppers, raspberries, stonefruits (except plums/fresh prunes), strawberries, and canola, including livestock commodities associated with canola in animal feed. A vinclozolin tolerance summary is presented below.

To enable the Agency to make a "reasonable certainty of no harm" find for succulent beans, canola and related tolerances and to establish three year time-limited tolerances for residues of vinclozolin and its metabolites containing the 3,5-DCA moiety in or on these commodities, BASF sought to reduce the risk posed by exposure to vinclozolin by requesting a phase-out over the next four years of all domestic food uses of vinclozolin except for the use on canola, and the revocation of all import tolerances except wine grapes. Tolerances related to the deleted uses will be revoked during the appropriate time period following use cancellation. The time frames for use cancellation are published in the Federal Register (65 FR 64051, September 20, 2000) (FRL-6744-2). On September 18, 2000, EPA received objections to the newly-issued tolerances on succulent beans and canola. Once EPA finalizes its response to the objections, it will amend its reregistration and reassessment decisions, if any such amendment is necessary.

Table 13. Tolerance Summary for Vinclozolin

Commodity	Current Tolerance, ppm	Time-limited Tolerance Expiration Date	Tolerance Reassessment, ppm	Comment
Tolerances Listed Under 40 CFR §180.380				
Beans, succulent	2.0	9/30/03	Revoke	Contingent upon re-issuance of the tolerance, the registrant will voluntarily cancel use in July 2004 and the tolerance will be revoked after use is cancelled.
Belgian endive, tops	5.0	None	Revoke	Registrant will voluntarily cancel use in December 2001. Tolerance will be revoked after use cancellation. It was recommended that the tolerance be reduced to 2.0 ppm, however, the tolerance is expected to be revoked shortly after the last legal use date for chicory on November 30, 2003.
Cucumbers	1.0	None	Revoke	As per the registrant's request, EPA will propose to revoke the tolerance in January 2001
Grapes (wine)	6.0	None	6.0	Import tolerance only, no U.S. registrations
Kiwifruit	10.0	None	Revoke	Registrant will voluntarily cancel use in December 2001. Tolerance will be revoked after use is cancelled.
Lettuce, leaf and head	10.0	None	Revoke	Registrant will voluntarily cancel use in July 2004. Tolerance will be revoked after use is cancelled.
Onions (dry bulb)	1.0	None	Revoke	Registrant has proposed voluntary cancellation on onions. The tolerance will be revoked after use cancellation. It was concluded that the tolerance for vinclozolin in/on bulb onions should be increased from 1.0 ppm to 6.0 ppm. However, the tolerance is expected to be revoked shortly after the last legal use date for onions, in September 2001.
Peppers (bell)	3.0	None	Revoke	As per the registrant's request, EPA will propose to revoke the tolerance in January 2001
Raspberries	10.0	None	Revoke	The registrant has proposed voluntary cancellation. Data support reassessment of the tolerance to 5.0 ppm, however, the tolerance is expected to be revoked shortly after the last legal use date in September 2001.

Commodity	Current Tolerance, ppm	Time-limited Tolerance Expiration Date	Tolerance Reassessment , ppm	Comment
Stone fruits, except plums/fresh prunes	25.0	None	Revoke	*Use* was deleted in September 1998. Tolerance revocation will be proposed shortly.
Strawberries	10.0	None	Revoke	*Use* was deleted in September 1998 Tolerance revocation will be proposed shortly.
Canola	1.0	9/30/03	1.0	Tolerance established July 18, 2000
Cattle, fat	0.05	9/30/03	0.05	Tolerance established July 18, 2000
Cattle, mbyp	0.05	9/30/03	0.05	Tolerance established July 18, 2000
Cattle, meat	0.05	9/30/03	0.05	Tolerance established July 18, 2000
Eggs	0.05	9/30/03	0.05	Tolerance established July 18, 2000
Goats, fat	0.05	9/30/03	0.05	Tolerance established July 18, 2000
Goats, mbyp	0.05	9/30/03	0.05	Tolerance established July 18, 2000
Goats, meat	0.05	9/30/03	0.05	Tolerance established July 18, 2000
Hogs, fat	0.05	9/30/03	0.05	Tolerance established July 18, 2000
Hogs, mbyp	0.05	9/30/03	0.05	Tolerance established July 18, 2000
Hogs, meat	0.05	9/30/03	0.05	Tolerance established July 18, 2000
Horses, fat	0.05	9/30/03	0.05	Tolerance established July 18, 2000
Horses, mbyp	0.05	9/30/03	0.05	Tolerance established July 18, 2000
Horses, meat	0.05	9/30/03	0.05	Tolerance established July 18, 2000
Milk	0.05	9/30/03	0.05	Tolerance established July 18, 2000
Poultry, fat	0.1	9/30/03	0.1	Tolerance established July 18, 2000
Poultry, meat	0.1	9/30/03	0.1	Tolerance established July 18, 2000
Poultry, mbyp	0.1	9/30/03	0.1	Tolerance established July 18, 2000
Sheep, fat	0.05	9/30/03	0.05	Tolerance established July 18, 2000
Sheep, mbyp	0.05	9/30/03	0.05	Tolerance established July 18, 2000
Sheep, meat	0.05	9/30/03	0.05	Tolerance established July 18, 2000

Import Tolerances

Once a pesticide use is no longer registered in the United States, the related pesticide residue tolerance is generally no longer needed. It is EPA's policy to propose revocation of a tolerance following the deletion of a related food use from a registration. The Agency has accepted BASF's requests and will process the above use deletions and proposed tolerance revocations.

The Agency recognizes, however, that interested parties may want to retain a tolerance and/or food/feed additive regulation in the absence of a U.S. registration, to allow legal importation of food into the U.S. To assure that all food marketed in the U.S. is safe, under FFDCA, EPA requires the same technical chemistry

and toxicology data for such import tolerances (tolerances without related U.S. registrations) as are required to support U.S. food use registrations and any resulting tolerances. See 40 CFR Part 158 for EPA's data requirements to support domestic use of a pesticide and establishment and maintenance of a tolerance and/or food/feed regulation. In addition, EPA requires residue chemistry data (crop field trials) that are representative of growing conditions in exporting countries in the same manner that EPA requires representative residue chemistry data from different U.S. regions to support domestic use of the pesticide and the tolerance and/or regulation.

Parties interested in supporting an existing tolerance as an import tolerance should ensure that all of the data noted above are available to EPA during its further assessments of existing tolerances, so that the Agency may determine whether maintenance of the tolerance and/or regulation would be protective of the public health.

Codex Harmonization

Codex MRLs have been established for plant and animal commodities. Codex and U.S. tolerance definitions are presently equivalent as both are expressed as the sum of residues of vinclozolin and all metabolites containing the 3,5-DCA moiety. Codex MRLs and U.S. tolerances are in harmony for the following commodities: cucumbers, kiwifruit, onions, peppers, strawberries, cattle meat, cattle milk, and poultry egg and succulent beans. Compatibility with the Codex tolerance limit in/on stonefruits is not possible at this time as the Codex MRL is 5 ppm on these fruits and the U.S. tolerance is 25 ppm on the stone fruit crop grouping. There is a pending petition to lower the 25 ppm U.S. stone fruit tolerance to 5 ppm, the same as Codex; however, the Agency intends to revoke the tolerance shortly. The following U.S. tolerances cannot be made compatible with the Codex values because data indicate the need for higher values: grapes, lettuce, raspberries. The chicken meat MRL (0.05 ppm) is not in harmony with the tolerance in poultry meat (0.1 ppm) due to recovery discrepancies with the analytical method.

Residue Analytical Methods

Plants: Adequate analytical methodology is available for data collection and enforcing tolerances of vinclozolin *per se* and its metabolites containing the 3,5-DCA moiety in/on plant commodities. Method I in PAM, Vol. II, which underwent a successful EPA method validation on strawberries, involves base hydrolysis of residues to convert vinclozolin and its metabolites to 3,5-DCA. After steam distillation and organic solvent extraction, the isolated DCA is derivatized to N-(3,5- dichlorophenyl) chloroacetamide using chloroacetyl chloride prior to quantitation by gas chromatography/ electron capture detection (GC/ECD). The limit of quantitation is 0.05 ppm.

Livestock: EPA has concluded that the following methods are available for the enforcement of tolerances for livestock tissues: method A9004A, a GC/ECD method, and method A9207, a High Performance Liquid Chromatography method. Method A9004A is based on conversion of vinclozolin and its metabolites to 3,5-DCA. However, it does not distinguish between residues of vinclozolin and other compounds convertible to 3,5-DCA. The LOQ is generally 0.05 ppm (0.1 ppm for poultry commodities). To confirm that the 3,5-DCA detected by method A9004A is derived from vinclozolin, method A9207 is

used to measure 2,3,4-trihydroxy-w-methylbutanoic acid-(3,5-dichloroanilide) (BF 352- 25), the major metabolite of vinclozolin in livestock commodities. The LOQ and the limit of detection are estimated to be 0.05 and 0.025 ppm, respectively. Both methods have been successfully validated.

The FDA PESTDATA database dated 1/94 (PAM, Vol. I, Appendix II) indicates that vinclozolin is completely recovered (> 80%) using FDA Multiresidue Protocols D and E (oily and non-oily matrices). Vinclozolin metabolite B is completely recovered using Protocols D and E (for oily matrices), and only partially recovered (50-80%) using Protocol E for non-oily matrices. Metabolite E is completely recovered using Protocol D. Metabolite F is recovered using Protocol D but no quantitative information is available. Metabolite S is partially recovered using Protocol E (non-oily matrices). The FDA multiresidue methodology differentiates between vinclozolin and iprodione, a pesticide that also contains the DCA moiety.

E. Regulatory Rationale

The following is a summary of the rationale for managing risks associated with the use of vinclozolin. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Mitigation

a. Dietary (Food) Risk Mitigation

(1) Acute Dietary (Food)

Assuming all currently registered foods are treated, acute dietary risk from vinclozolin in food is above the Agency's level of concern at the 99.9th percentile of exposure with 120% of the aPAD utilized. As described earlier, the Agency believes that basing its exposure estimate on the very upper ranges of potential exposure (i.e. 99.5th and above) will unreasonably overestimate exposure. The %aPAD is below 100% at the 99.85th percentile of exposure. Therefore, no additional risk mitigation is currently required. In addition, the registrant is already proposing to reduce dietary exposure. After the immediate use deletions on onions and raspberries, acute risk from food will be < 100% of the aPAD.

(2) Chronic (Non-cancer and Cancer) Dietary (Food)

Chronic dietary risk from food is well below the Agency's level of concern. All chronic (non-cancer) %PADs for all subgroups were ≤7%. Therefore, no mitigation measures are necessary at this time to address chronic dietary risk from food.

(3) Carcinogenic (overall antiandrogenic) Dietary (Food)

The Agency has determined that use of the most sensitive toxicity endpoint and the full FQPA safety factor would be protective of the antiandrogenic effects, including carcinogenic effects for all populations. As in the case of chronic dietary, %PADs for all subgroups were $\leq 7\%$. Therefore, no mitigation measures are necessary at this time to address cancer dietary risk from food.

(4) Carcinogenic Dietary: 3,5-DCA (food)

The Agency generally considers 1×10^{-6} (1 in 1 million) or less to be negligible for cancer. The results of this analysis indicate that the cancer dietary risk of 2.6×10^{-7}, associated with all currently registered uses, is below the Agency's level of concern. Therefore, no mitigation measures are necessary at this time to address cancer dietary risk from 3,5-DCA in food.

b. Dietary (Drinking Water) Risk Mitigation

Acute: For vinclozolin, acute DWLOCs were calculated for those percentiles of exposure resulting in apparent risks below 100% aPAD. At all but the very highest percentiles of exposure (99.85th and above), the DWLOC for vinclozolin is greater than the EECs in surface and ground water. As stated in the dietary (food) sections, given the level of refinement in the vinclozolin exposure estimate, using the highest percentile of exposure overstates risk. Model estimates (EECs) of potential drinking water exposure from ground and surface water sources do not exceed the acute DWLOC values (at the 99.85th percentile) and therefore, are below the Agency's level of concern. No mitigation measures are necessary at this time.

Chronic (Non-cancer and cancer): The comparison between the DWLOC of 11 ppb for the most sensitive population (children 1-6 years old) and the highest chronic EEC of 9.4 ppb for vinclozolin indicate a lack of chronic/cancer dietary risk concern for drinking water sources. Therefore, no risk mitigation measures are necessary at this time.

Cancer for 3,5-DCA: Potential exposure from surface and ground drinking water sources exceed the Agency's level of concern for cancer dietary risk from vinclozolin-derived 3,5-DCA. The Agency believes it is likely that there is no risk of concern from exposure to vinclozolin-derived 3,5-DCA. However, 3,5-DCA exhibits fate properties (high mobility and moderate persistence) of pesticides which may be found in ground and surface waters. To address drinking water concerns, the registrant of vinclozolin must submit the following confirmatory data. These data will be requested shortly in a separate Data Call-in Notice.

Surface Water and Ground Water Monitoring Studies
The registrant must initiate a surface and ground water monitoring program. A meeting between the registrant and the Agency will be scheduled to discuss the protocols of the studies.

The following advisory language is necessary for all vinclozolin product labels:

Ground Water Label Advisory
"Vinclozolin has a degradation product with properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination."

Surface Water Label Advisory
"Under some conditions, vinclozolin degradates may have a high potential for runoff into surface water. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain surface water."

Pending review of the final report of the drinking water monitoring studies, no mitigation measures to address drinking water concerns, beyond the ground and surface water label advisory, are necessary at this time.

c. Non-Dietary Risk Mitigation

Post-application risks to the general population were considered for golfers following treatment of greens, tees, and fairways. The risk to adult and child golfers is below the Agency's level of concern on the day of application. This lack of concern for golfers is expected considering that golfers are only walking on the treated turf.

The multiroute MOE for toddlers playing on turf treated at a sodfarm is unacceptable on the day of application and risk does not fall beneath the Agency's level of concern until 24 days after application. To mitigate the unacceptable risk resulting from exposure before the 24 day period has elapsed, the registrant has submitted label amendments deleting use on sod farms (except for transplant onto golf courses), and have restickered all products in the channels of trade to require a 24 day period before sod can be harvested. It is assumed that, at a minimum, sod harvesting and replanting in a residential setting would take an additional two days; thereby, providing a total of 26 days for residues of vinclozolin to decline to an acceptable level. EPA believes that these risk reduction measures when taken into consideration with the conservative exposure scenario and exposure assumptions, immediately reduce risk such that it is below the Agency's level of concern. No additional non-occupational risk mitigation is necessary at this time.

d. Aggregate Risk Mitigation (Vinclozolin)

The acute, chronic, and carcinogenic aggregate risk assessments considered only food and drinking water sources of exposure which have already been discussed in the dietary risk mitigation section. The aggregate short-term and intermediate-term risk assessment includes the non-occupational component in addition to food and drinking water sources of exposure. Short-term and intermediate-term aggregate risks were calculated for children at the sod harvest interval of 24 days to determine the relative contribution of

food, water and sod and to determine if a PHI longer than 24 days is necessary to be protective of aggregate risk to children. The 24 day PHI is protective of toddlers in terms of aggregate risk. The aggregation of child golfer exposure with food, water and sod exposure sources is considered unlikely and inappropriate. No additional aggregate risk mitigation is necessary because the registrant has already restickered all products in the channels of trade to add a 24 day PHI for sod harvested for transplant to inhabited residences. The registrant also submitted label amendments on July 15, 2000 to only permit sod produced for transplant for the establishment or renovation of golf course landscapes.

e. Aggregate Risk Mitigation (3,5-DCA)

EPA considered the relative contribution of vinclozolin-, iprodione- and procymidone-derived 3,5-DCA.

Vinclozolin: Cancer risks due to food sources of exposure alone are below the Agency's level of concern. However, the EECs in surface water and ground water exceed the DWLOC indicating a potential for concern.
Iprodione: The food risk associated with 3,5-DCA derived from iprodione is below the Agency's level of concern. The iprodione-derived 3,5-DCA carcinogenic DWLOC is exceeded for both surface and ground water.
Procymidone: The cancer risk associated with 3,5-DCA in imported wine produced from grapes treated with procymidone is below the Agency's level of concern. There is no drinking water exposure because procymidone is not registered in the U.S.

The cumulative, food-only cancer risk associated with 3,5-DCA derived from **all three** of these imide fungicides is 5.6×10^{-7}. The 3,5-DCA DWLOC from all three Imide fungicides including those currently registered vinclozolin uses not being supported after this use season is 0.26 ppb. The vinclozolin- and iprodione-derived 3,5-DCA EECs alone exceed the carcinogenic aggregate DWLOC indicating a potential for concern. As already stated, these risk numbers justify asking for monitoring data for 3,5-DCA in both ground and surface water. The registrants of both vinclozolin and iprodione must submit the data. These data will be requested shortly in a separate Data Call-in Notice.

f. Occupational Risk Mitigation

To address short- and intermediate-term risks from dermal and/or inhalation exposure to handlers and post-application workers, mitigation measures are necessary. Risk from occupational exposure to ornamentals, raspberries, and onions will not be addressed because these uses are no longer being supported by the registrant.

(1) Short- and Intermediate-term Handler Risk Mitigation

Only risk from exposure to the extruded granular product is considered in this section. BASF, the sole technical registrant, no longer manufactures the liquid flowable formulation. Due to the voluntary

cancellation request on ornamentals, BASF no longer intends to manufacture or market the dry flowable formulation. Therefore, occupational risk estimates based on these formulations will not be considered and are not eligible for reregistration. Note that the extruded granular product is only sold in water-soluble packaging.

Currently required handler PPE includes coveralls over long-sleeved shirt and long pants, chemical resistant gloves, chemical-resistant footwear plus socks, protective eyewear, chemical resistant headgear for overhead exposure, and a chemical resistant apron when mixing, loading, or cleaning equipment. This level of dermal protection is protective for most handler scenarios, presents no additional burden for handlers of vinclozolin products, and will be retained[6]. Only one handler scenario requires an increase in protection. An acceptable MOE is not reached until engineering controls are employed (i.e. an enclosed cab) when applying sprays to kiwifruit with an airblast sprayer. End-use labels currently require a respirator with an organic vapor-removing cartridge in enclosed areas and a dust/mist respirator for outdoor exposures. EPA has determined that these respirator requirements are unnecessary because the dermal pathway is the major route of exposure and the risk assessment indicates that additional protection provided by respirators is minimal.

Note that for aerial applicators, PHED provides estimated exposures for **enclosed** fixed-wing aircraft only; therefore, the calculated dermal and inhalation exposure and risks for aerial applicators are based on engineering controls (i.e., enclosed cockpits). The Agency believes that there are very few, if any aerial applicators who do not already utilize enclosed cockpits. Therefore, the impact and burden to require aerial applicators to be in enclosed cockpits will be negligible. For these reasons, the Agency has determined that enclosed cockpits for aerial applicators should be specified on vinclozolin product labels.

Under the Worker Protection Standard, enclosed cabs and enclosed cockpits qualify as closed systems. Handler employers may allow handlers to omit some of the PPE listed on the pesticide labeling for a handling task if the handlers are using a closed system.

Workers performing handling tasks on golf course establishments or who are involved in post-harvest application to chicory roots are not within the scope of the Worker Protection Standard. Since potential handler exposure is indistinguishable for WPS and nonWPS uses, the active ingredient specific handler requirements on labeling will be the same for WPS and nonWPS uses.

(2) Chronic and Cancer Handler Risk Mitigation

Chronic and cancer exposure scenarios were only evaluated for a very limited number of uses that are allowable in the ornamental/floriculture marketplace. These chronic exposure scenarions have not been considered in this document due to the registrant's voluntary cancellation request on ornamentals.

---

[6] Mixers/Loaders may wear reduced PPE because they are performing a handler task using a closed system (water soluble packaging).

(3) Other Handler Risk Mitigation

Workers may also be exposed to vinclozolin during chicory root packing. According to a chicory root producer, the following is a summary of the protocol for chicory roots: Roots are dug from the ground and cleaned on the digger. They are moved to a dump truck which takes them to the root packing area. The roots are dumped onto a line where they are cleaned again. At this point, the roots are placed in a bin for cold storage. Just before the roots go into the bin, they are sprayed with Ronilan®. All spraying takes place outdoors and the system operates under low pressure. The spray nozzles are positioned above and below a chain belt with plastic guards positioned around this particular area of the belt. Once a bin is full, it is moved from the spray area and placed inside a dry van for shipment to cold storage. The producer noted that workers who are near the spray system wear "a rainsuit, gloves and eye protection so as to avoid any contact with the Ronilan®". Although workers who are near the spray system in the chicory root processing are not technically considered "handlers" under the WPS, there is an unquestionable potential for exposure. Therefore, the following statement must be added to the 24(c) label for chicory grown for Belgian endive:

> "Employers must ensure that workers in the spray area wear the same personal protective equipment (PPE) as required for applicators, specifically, coveralls over long-sleeved shirt and long pants, chemical resistant gloves, chemical resistant footwear, and chemical-resistant headgear if overhead exposure. The employer must provide, clean, and maintain all PPE. "

Employers are encouraged to require more protective equipment, such as a chemical-resistant suit, based on professional judgement.

(4) Post-Application Exposure

Postapplication risks are mitigated by the Agency using an administrative control measure which is referred to as the Restricted Entry Interval (REI) which represents the amount of time required for residues to dissipate in treated areas prior to beginning a job or task in that area such that the resulting exposures do not exceed the Agency's level of risk concern. Post-application risk mitigation was not considered for onions, raspberries and ornamentals because these uses are not being supported by the registrant.

Based on the risk assessment, the following REIs should be increased:

- Lettuce: From 12 hours to 7 days*
- Kiwi: From 1 day to 6 days
- Turf: From 12 hours to 5 days (sodfarm use only)

The following REIs may be decreased:

- Snap beans: from 10 days to 7 days
- Canola: from 9 days to 7 days

*REI for lettuce: The REI for hand harvesting lettuce is 11 days. EPA sets the REI on the activity which has the highest potential for exposure, in this case harvesting. However, the PHI of 28 days guarantees that harvesters will not enter the field until 28 days have passed. Additionally, it is not expected that the PHI will be modified in the future as this use is expected to be phased-out in 2004. Therefore, the REI for lettuce will be set on the lower exposure activities including scouting, irrigating, thinning, and weeding.

*REI exception for lettuce: The Agency estimated that a 7 day REI is necessary for scouting, weeding and irrigating mature/high foliage lettuce, but a shorter REI is protective for scouting, irrigation, and thinning of immature/low foliage lettuce because the smaller plants result in lower exposure to the workers. To avoid creating compliance and enforcement problems, one REI will be set for lettuce based on the likely high-exposure activities related to high foliage lettuce, and a labeling exception to the REI may be added for weeding, thinning, and irrigating the lower foliage/immature lettuce.

CROP	REI	EXCEPTIONS
Lettuce	7 days	In addition to the early-entry exceptions specified in the WPS: - For applications to lettuce taking place **within 35 days of planting**, workers may enter to perform thinning, weeding, or irrigation tasks after 24 hours provided they are wearing at least long sleeved shirt, long pants, shoes and socks. Crop producers must be able to verify planting dates if they want to take advantage of the exception.

Non-WPS entry restrictions: The risk is acceptable on the day of application for typical golf course maintenance activities such as fertilizing or mowing. Therefore, no entry restrictions are required (after sprays have dried) for this use site.

REIs vs. PHIs: Growers should be aware that they are required to follow both the PHI and the REI to avoid using the pesticide in a manner inconsistent with its labeling.

Double notification: EPA has determined that double notification is required. The WPS calls for "double notification" (both posting of treated areas and oral warnings) for active ingredients when a single exposure could cause unacceptable risk, for example, for active ingredients posing developmental or reproductive risks. Vinclozolin falls into this category as there is concern for inadvertent one-time exposures to vinclozolin. All labels must contain the following statement:

"Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas".

Note to Crop Advisors: The registrant should add the following advisory statement to labels:

"Users should inform certified crop advisors [as defined by the Worker Protection Standard (WPS)] that people engaged in scouting activities should wear early entry PPE when entering treated areas during the first [insert length of REI] following application."

Early entry: Early entry workers must wear:

- Coveralls over a long-sleeved shirt and long pants
- Chemical resistant gloves
- Chemical resistant footwear plus socks
- Chemical resistant headgear, if overhead exposure

2. Environmental Risk Mitigation

In addition to the human health risks, the Agency is also concerned with ecological risks potentially caused by the use of vinclozolin. Even when assuming average use rates, chronic RQs for birds exceed the level of concern; however, these exceedences are relatively low. Raspberry use poses the greatest risk, with turfgrass/ornamental use next, then onions and lettuce, then snap beans and finally, the canola use exhibiting the least risk.

The registrant has already asked for the phase-out of all uses except turf and canola. For canola, all avian chronic RQs are below the level of concern assuming average use rates. For turfgrass, the highest RQ is 2.7, which is above the LOC of 1.0. The registrant has undertaken several mitigation measures on turf during the last few years which reduce risk to nontarget species on turf.

In 1998, BASF restricted turf use to ground application methods only. Air application instructions have been removed from the turf labels. The high curative rates (5.5 lbs ai/acre/application) were removed from labels. The total seasonal rate was decreased from 5.5 lbs ai/acre/year to 4 lbs ai/acre/year and the number of allowable applications was reduced from 4 to 3 in one year. BASF also restricted the area of the golf course which can be treated to tee boxes, greens, and turf mowed at 1" or less.

More recently, BASF has further restricted turf use. Use on sod produced for transplant was restricted to sod produced for the establishment or renovation of golf course landscapes only. BASF also eliminated the commercial use pattern on turf (lawn and landscape areas at business and office complex sites and turf at professional sports complexes or arenas). Therefore, use on turf is limited to certain areas on golf courses, sod transplanted onto golf courses, and manufacturing/industrial sites. The Agency believes that the risk reduction measures BASF has initiated, including cancellation of most uses and several turf use restrictions, greatly reduce risk to avian species such that it is below the Agency's level of concern.

In regard to chronic risks to freshwater fish and invertebrates, data are lacking. The Agency has requested these data in a previous Data Call-In and the registrant is currently preparing to submit the studies.

3. Other Labeling

To be eligible for reregistration, other use and safety information needs to be placed on the labeling of all end-use products containing vinclozolin. For the specific labeling statements, refer to Section V of this document.

a. Endangered Species Statement

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989), and is providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, but subject to change as the final program is developed, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program, which may be altered from the interim program, will be described in a future Federal Register notice. The Agency is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

b. Spray Drift Management

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices, State Lead Agencies for pesticide regulation, and other parties to develop the best spray drift management practices. The Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling as specified in Section V of this document. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast, and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate. In the interim, the following spray drift related language is required on product labels that are applied outdoors in liquid sprays (except mosquito adulticides), regardless of application method: "Do not allow this product to drift."

VI. What Registrants Need to Do

In order to be eligible for reregistration, registrants need to implement the risk mitigation measures outlined in Section IV, by submitting label amendments and meeting the data requirements described in this section.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of vinclozolin for the eligible uses has been reviewed and determined to be substantially complete. The following outstanding or confirmatory data are necessary to complete the generic database and/or refine the risk assessments:

Table 14. Data Requirements for Vinclozolin

Guideline Test Name	New Guideline No. (OPPTS)	Old Guideline No. (OPP)
Certification of Ingredient Limits	830.1750	62-2
Developmental neurotoxicity study (modified protocol)	870.6300	83-6
Aerobic soil metabolism	835.4100	162-1
Leaching and adsorption/desorption	835.1230 & 835.1240	163-1
Aquatic invertebrate life-cycle	850.1300	72-4(b)
Freshwater fish life-stage	850.1400	72-4
Freshwater fish life-cycle	850.1500	72-5
Surface water monitoring study	NA	NA
Ground water monitoring study	NA	NA

Toxicology Studies

Developmental Neurotoxicity (870.6300). The Agency has determined that a developmental neurotoxicity (DNT) study is warranted; however, the kinds of perturbations likely to occur with androgen/estrogen disruptor cannot be identified by the standard guideline DNT study. The Agency is working to develop a small internal steering committee to determine how to appropriately modify the study to assess the potential effects of vinclozolin in brain development. Consequently, the DNT study will be due 3 years after the Agency determines the protocol necessary to assess the relevant endpoints. This study was also listed as a requirement for the conditional registration of canola and snap beans.

Chronic/oncogenicity studies (870.4200) would be useful to estimate the carcinogenic potential of the toxic degradate 3,5-DCA. However, since p-chloroaniline is more reactive than 3,5-dichloroaniline, the Agency is confident that 3,5-DCA is less carcinogenic than PCA to some degree. Therefore, the registrant should decide whether it is in their best interest to conduct the cancer studies in order to demonstrate a lower risk from 3,5-DCA.

Chemistry Studies

Certification of Ingredient Limits (830.1750). The submitted data do not satisfy the requirement because the same value is listed for the nominal concentration and the upper certified limit of the active ingredient on the Confidential Statement of Formula (CSF). The registrant must submit a revised CSF which resolves this discrepancy.

A vinification study to determine degradation/metabolism during the wine fermentation process was requested at the time when canola and snap beans were conditionally registered. The study is due in 2003.

Environmental Fate and Ecological Effects Studies

Vinclozolin environmental fate and effects data are not sufficient in certain areas. The ecotoxicity studies were required in a previous DCI and are still outstanding. The registrant has been notified of the data gaps and is in the process of submitting the studies.

Enviromental Fate: Basic fate information is needed to understand the persistence and mobility of the degradates. Additionally, the water monitoring data will be much less useful without lab data to help interpret the field results.

- **Aerobic soil metabolism (835.4100).** Frozen storage stability data for individual analytes (metabolites B, D, and E) in soil are needed.
- **Leaching and adsorption/desorption (835.1230 & 835.1240).** Metabolite B is an important degradate and K_d values for four soils should be submitted. K_{ds} for metabolite B will enable a more precise assessment of the potential mobility of this key degradation product, which is formed early in the degradation process in relatively large concentrations. In addition, this information may help in modeling simulations that assess the potential of vinclozolin residues to contaminate surface waters. Soil column studies indicate that metabolite B is potentially mobile, but the information available from these studies is only qualitative.

Surface/Groundwater Monitoring:

- The registrants for vinclozolin and iprodione will be issued a Data Call-in, separate from the generic Data Call-in this RED document, requiring surface water and ground water monitoring studies. The study designs and the methods for sample analysis will be discussed in upcoming meetings with the registrants.

Ecotoxicity:

- **Aquatic invertebrate life-cycle (freshwater and marine) (850.1300).** The need for these studies is high because vinclozolin and its degradates may be relatively persistent and repeated applications result in repeated exposure.
- **Freshwater fish life-cycle and life-stage.** The need for these studies is high because vinclozolin is relatively persistent and repeated applications result in repeated exposure. The following are still outstanding:
  - freshwater fish life-cycle study with technical vinclozolin (850.1500)
  - freshwater fish life-stage study with technical vinclozolin (850.1400)
  - freshwater fish life-stage study with metabolite B (850.1400)
  - freshwater fish life-stage study with metabolite E (850.1400)

2. Labeling for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing-use product (MUP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MUP labeling must bear the labeling contained in the table at the end of this section, and include the restriction on formulating vinclozolin only as an extruded granular product in water soluble packaging. The Product Reregistration Branch (PRB) contact is Jane Mitchell at (703) 308-8061.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to implement these changes is specified in Table 15 at the end of this section. The Product Reregistration Branch (PRB) contact for vinclozolin is Jane Mitchell at (703) 308-8061.

C. Label Summary Table

Table 15. Summary of Label Changes for Vinclozolin		
Description	**Labeling**	**Placement on Label**
Manufacturing Use Products		
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may only be used to formulate the extruded granular product which must be packaged in water soluble bags."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	

Description	Labeling	Placement on Label
End Use Products Intended for Occupational Use (all uses within the scope of WPS)		
Handler PPE requirements established by the RED, [a] (only extruded granular formulations packaged in water soluble packages are eligible for reregistration)	"Personal Protective Equipment (PPE)" Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart." Mixers and loaders must wear: • Long-sleeved shirt and long pants • Socks and shoes • Chemical resistant gloves • Chemical resistant apron Applicators*, flaggers and other handlers must wear: • Coveralls over long-sleeved shirt and long pants, • Chemical resistant gloves, • Chemical resistant footwear plus socks, • Chemical resistant headgear (if overhead exposure), • Chemical resistant apron when cleaning equipment" "* See engineering controls below for additional requirements"	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them." "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Users should inform Certified Crop Advisors [as defined by the Worker Protection Standard (WPS)] that people engaged in scouting activities should wear early entry PPE when entering treated areas during the first [insert REI of crop] following application."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Description	Labeling	Placement on Label
User Safety Requirements for 24(c) products used on chicory	"Employers must ensure that workers in the spray area wear the same personal protective equipment (PPE) as required for applicators, specifically, coveralls over long-sleeved shirt and long pants, chemical resistant gloves, chemical resistant footwear, and chemical-resistant headgear for overhead exposure. The employer must provide, clean, and maintain all PPE. "	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
Engineering Controls	"Engineering Controls" "When handlers use enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS." "Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for Agricultural Pesticides [40 CFR 170.240(d)(6)]." "Applicators using airblast equipment must be in an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides for dermal protection, and: • may wear long-sleeved shirt and long pants, socks and shoes, • must have immediately available for use in case they must leave the cab: coveralls, chemical resistant gloves, chemical resistant footwear, and chemical resistant headgear for overhead exposure, • take off any PPE that was worn in the treated area before reentering the cab, and • store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab." This product is formulated into water-soluble packets and when used correctly, it qualifies as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must : ' • wear the personal protective equipment required above for mixers and loaders, and • be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown, coveralls and chemical resistant footwear.	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)

Description	Labeling	Placement on Label
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards	"Environmental Hazards" "This product is toxic to fish. Do not apply directly to water, or to areas where water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters." *Ground Water Advisory* "Vinclozolin has a degradation product with properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination." *Surface Water Advisory* "Under some conditions, the vinclozolin degradate 3,5-DCA may have a high potential for runoff into surface water (primarily via dissolution in runoff water). These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain surface water."	Precautionary Statements under Environmental Hazards

Description	Labeling	Placement on Label
Restricted-Entry Intervals For WPS products as required by Supplement Three of PR Notice 93-7	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of: For kiwi: 6 days For sod farm turf: 5 days For snap beans: 7 days For canola: 7 days For lettuce: 7 days" Exception for lettuce: "In addition to the early-entry exceptions specified in the WPS: For applications to lettuce taking place **within 35 days of planting**, workers may enter to perform thinning, weeding, or irrigation tasks after 24 hours provided they are wearing at least long sleeved shirt, long pants, shoes and socks. Crop producers must be able to verify planting dates if they want to take advantage of the exception."	Directions for Use, Agricultural Use Requirements Box
Early Re-entry Personal Protective Equipment for Products subject to WPS as required by Supplement Three of PR Notice 93-7.	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:" • "coveralls over a long-sleeved shirt and long pants, • chemical-resistant gloves, • chemical resistant footwear plus socks, • chemical-resistant headgear (if overhead exposure)."	
Double notification	"Notify workers of the application by warning them orally and by posting warning signs at entrances to treated area."	
Early Re-entry for non-WPS Occupational Use Products	"Entry Restriction: do not enter or allow others to enter until sprays have dried."	

Description	Labeling	Placement on Label
Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application." "Do not allow this product to drift." In addition to the current restrictions on turf labels, the following additional restrictions must be added: "This product may only be used as follows: **Industrial:** lawn and landscape areas at manufacturing sites and industrial parks. **Golf Course:** tee boxes, greens and turf mowed at 1" or less and turf produced for construction or renovation of golf course landscape only."	Place in the Direction for Use directly above the Agricultural Use Box.
Application Restrictions	In addition to the current restrictions on turf labels, the following additional restrictions must be added: - "Do not apply this product to turf for transplant purposes except for sod produced for golf course establishment or renovation. - Do not apply to turf at locations serving as residences. - Do not treat sod produced for transplant to residential or commercial landscapes."	Place in the General Restrictions and Limitations section
Spray Drift language that must be placed on each product that can be applied aerially:	"Aerial Spray Drift Management" "Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions."	Directions for Use
The following language must be placed on each product that can be applied aerially:	"The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations. 1.The distance of the outermost nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor. 2.Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees. Where states have more stringent regulations, they should be observed. The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information."	Directions for Use

Description	Labeling	Placement on Label
The following language must be placed on each product that can be applied aerially:	"Aerial Drift Reduction Advisory" "This section is advisory in nature and does not supersede the mandatory label requirements." **"INFORMATION ON DROPLET SIZE"** "The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions)."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"CONTROLLING DROPLET SIZE"** "●Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets. ●Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure. ●Number of nozzles - Use the minimum number of nozzles that provide uniform coverage. ●Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential. ●Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"BOOM LENGTH"** "For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width."	Directions for Use

Description	Labeling	Placement on Label
The following language must be placed on each product that can be applied aerially:	**"APPLICATION HEIGHT"** "Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"SWATH ADJUSTMENT"** "When applications are made with a crosswind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)"	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"WIND"** "Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"TEMPERATURE AND HUMIDITY"** "When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry."	Directions for Use

Description	Labeling	Placement on Label
The following language must be placed on each product that can be applied aerially:	**"TEMPERATURE INVERSIONS"** "Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"SENSITIVE AREAS"** "The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas)."	Directions for Use

[a] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

D. Existing Stocks

Use Cancellations: The following table specifies the time frames for the phase-out of several uses. These time frames were published in the Federal Register on September 20, 2000 (65 FR 64051, FRL-6744-2) for public comment. In response to the notice, comments were received from representatives of the ornamental industries and the National Onion Association and EPA is currently in the process of considering these comments. EPA's response to these comments and/or amendments to the existing stocks provisions for these two uses will be published in an upcoming "close-out" Federal Register notice.

The distribution or sale of stocks by registrants will not be lawful under FIFRA after the sale and distribution dates listed in the table, except for the purposes of returns and relabeling, shipping such stocks for export consistent with the requirements of Section 17 of FIFRA, or for proper disposal. Retailers, distributors, and end-users may sell, distribute, or use products with previously approved labeling which have been released for shipment until such supplies are exhausted or the last legal use date presented in the table.

Commodity	Date of Use Cancellation Request	Last Date for Sale and Distribution of Existing Stocks	Last Date for Legal Use
Onions	July 15, 2000	TBD	TBD
Raspberries	July 15, 2000	January 1, 2001	September 30, 2001
Ornamentals	July 15, 2000	TBD	TBD
Kiwi 24(c)	December 31, 2001	December 31, 2002	November 30, 2003
Chicory 24(c)	December 31, 2001	December 31, 2002	November 30, 2003
Lettuce	July 15, 2004	July 15, 2005	September 30, 2005
Succulent beans	July 15, 2004	July 15, 2005	September 30, 2005

TBD = to be determined

Label Changes Specified in the RED: The Agency has determined that registrants may distribute and sell vinclozolin products bearing old labels/labeling for 12 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 24 months from the date of the issuance of this RED. **Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and the existing stocks requirements applicable to the use cancellations listed above.**

VII. Related Documents and How to Access Them

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: www.epa.gov/pesticides/op. The documents include those referenced in this RED, namely:

Anderson, David (USEPA/OPPTS/OPP/HED). *Vinclozolin: 2nd Report of the Hazard Identification Assessment Review Committee.* 12/8/99.

Angulo, Karen (USEPA/OPPTS/OPP/EFED). Transmittal of EFED Reregistration Eligibility Summary for Vinclozolin. (See addendum for updates). 6/6/96.

Dawson, Jeffrey (USEPA/OPPTS/OPP/HED). *The Revised Occupational and Residential Exposure Aspects of the HED Chapter of the Reregistration Eligibility Decision Document for Vinclozolin.* 2/8/00.

Federoff, N.E.(USEPA/OPPTS/OPP/EFED). *Errata for terrestrial assessment of revised uses, incorporating new aquatic toxicity data and endocrine disruption language for the EFED chapter of the vinclozolin RED.* 12/15/99.

Hazel, William (USEPA/OPPTS/OPP/HED). *Vinclozolin: Revised Human Health Risk Assessment.* 5/12/00.

Hazel, William (USEPA/OPPTS/OPP/HED). *Vinclozolin: Drinking Water Levels of Concern Attributable to Vinclozolin Alone and Three Dicarboximide Fungicides Combined.* 7/6/00.

Tarplee, Brenda (USEPA/OPPTS/OPP/HED). *Vinclozolin: Reassessment Report of the FQPA Safety Factor Committee.* 12/15/99.

Tarplee, Brenda (USEPA/OPPTS/OPP/HED). *Vinclozolin: Report of the FQPA Safety Factor Committee Regarding Recommendations for Cancer Risk Assessment.* 5/9/00.

Young, Dirk F. (USEPA/OPPTS/OPP/EFED). *3,5-DCA (vinclozolin degradate): Drinking Water EECs for golf course and canola use.* 7/10/00.

Young, Dirk F. (USEPA/OPPTS/OPP/EFED). *Vinclozolin and Its Degradates: Tier II Drinking Water EECs for Use in the Human Health Risk Assessment.* 2/4/00.

VIII.Appendices

Appendix A: Use Patterns Eligible for Reregistration

Application Type, Equipment	Formulation	Max. Single App. Rate (lb al/A)	Seasonal Max. (lbs al/A/Yr)	PHI (days)	REI (days)	Restrictions/ Comments
			Lettuce			
Foliar Spray - Ground equipment - Aerial	50% EG [7969-85]	1	3	28	7 (see comments)	An exception to the 7 day REI is established for applications to lettuce taking place within 35 days of planting. Under this exception, workers may enter to perform thinning, weeding or irrigation tasks after 24 hours.
			Canola			
Foliar Spray - Ground equipment - Aerial	50% EG [7969-85]	.5	.5	N/A	7	
			Snap beans			
Foliar Spray - Ground equipment - Aerial	50% EG [7969-85]	.5	1	10	7	Apply only to beans which will be mechanically harvested
			Kiwi			
Foliar Spray - Ground equipment	50% EG [7969-85] [CA-830044]	1	4	7	6	State of California only
			Chicory (roots used for the production of Belgian endive)			
Post harvest spray application on roots prior to cold storage or forcing	50% EG [7969-85] [CA890030]	Cold storage: 0.02 lb ai diluted in 4-5 gallons of water per metric ton of roots. Forcing: 0.002 lb ai diluted in 0.8	2 (once prior to cold storage, once prior to forcing)	30	N/A	Use limited to CA counties of Solano, Stanislaus, Merced, and Lassen.

Application Type, Equipment	Formulation	Max. Single App. Rate (lb ai/A)	Seasonal Max. (lbs ai/A/Yr)	PHI (days)	REI (days)	Restrictions/ Comments
Turf						
Spray - Ground equipment - Hand held equipment	50% EG [7969-85]	1.35	4	N/A	5 (REI applies to sod farm use only)	Sod farm use: Sod must be mechanically harvested. Cannot be applied to turf for transplant purposes except for sod produced for golf course establishment or renovation. Application to turf: Can only be applied to lawn and landscape areas at manufacturing sites, industrial parks, and to golf course turf mowed at 1" or less.

Appendix B: Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within the case 2740 (vinclozolin) covered by this RED. It contains generic data requirements that apply to vinclozolin in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

   A. Terrestrial food
   B. Terrestrial feed
   C. Terrestrial non-food
   D. Aquatic food
   E. Aquatic non-food outdoor
   F. Aquatic non-food industrial
   G. Aquatic non-food residential
   H. Greenhouse food
   I. Greenhouse non-food
   J. Forestry
   K. Residential
   L. Indoor food
   M. Indoor non-food
   N. Indoor medical
   O. Indoor residential

3. Bibliographic Citation (Column 3). If the Agency has acceptable data in its files, this column list the identify number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

Appendix B: Data Supporting Guideline Requirements for the Reregistration of Vinclozolin

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	all	41888901
61-2A	Start. Mat. & Mnfg. Process	all	41888901
61-2B	Formation of Impurities	all	41888901
62-1	Preliminary Analysis	all	41888902
62-2	Certification of limits	all	41888902
62-3	Analytical Method	all	41888902
63-2	Color	all	41626801
63-3	Physical State	all	41626801
63-4	Odor	all	41626801
63-5	Melting Point	all	41626801
63-7	Density	all	41626801
63-8	Solubility	all	41888903
63-9	Vapor Pressure	all	41888903
63-11	Octanol/Water Partition	all	41471003
63-12	pH	all	41626801
63-13	Stability	all	41626802
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	A,B,C	137322
71-2A	Avian Dietary - Quail	A,B,C	136365
71-2B	Avian Dietary - Duck	A,B,C	136366
71-4A	Avian Reproduction - Quail	A,B,C	136366, 42869801
71-4B	Avian Reproduction - Duck	A,B,C	41679801, 42827501
72-1A	Fish Toxicity Bluegill	A,B,C	127751
72-1C	Fish Toxicity Rainbow Trout	A,B,C	264302,41325101
72-2A	Invertebrate Toxicity	A,B,C	136371
72-3A	Estuarine/Marine Toxicity - Fish	A,B,C	44429901
72-3B	Estuarine/Marine Toxicity - Mollusk	A,B,C	44429902
72-3C	Estuarine/Marine Toxicity - Shrimp	A,B,C	44429903

Appendix B: Data Supporting Guideline Requirements for the Reregistration of Vinclozolin

REQUIREMENT		USE PATTERN	CITATION(S)
72-4A	Early Life Stage Fish	A,B,C	Data Gap
72-4B	Life Cycle Invertebrate	A,B,C	Data Gap
72-5	Life Cycle Fish	A,B,C	Data Gap
72-6	Aquatic Organism Accumulation	A,B,C	136387
122-2	Aquatic Plant Growth	A,B,C	423947-01 through -05
141-1	Honey Bee Acute Contact	A,B,C	40992801
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	A,B,C,I	86336
81-2	Acute Dermal Toxicity - Rabbit/Rat	A,B,C,I	86339
81-3	Acute Inhalation Toxicity - Rat	A,B,C,I	75474
81-4	Primary Eye Irritation - Rabbit	A,B,C,I	86341
81-5	Primary Dermal Irritation - Rabbit	A,B,C,I	86341
81-6	Dermal Sensitization - Guinea Pig	A,B,C,I	80451
82-1A	90-Day Feeding - Rodent	A,B,C,I	42714001, 44006102
82-2	21-Day Dermal - Rabbit/Rat	A,B,C,I	41471004
83-1A	Chronic Feeding Toxicity - Rodent	A,B,C,I	43254701, 43254702, 44430301
83-1B	Chronic Feeding Toxicity - Non-Rodent	A,B,C,I	40859501
83-2A	Oncogenicity - Rat	A,B,C,I	43254703
83-2B	Oncogenicity - Mouse	A,B,C,I	43254704
83-3A	Developmental Toxicity - Rat	A,B,C,I	41413001,43703301,44395701, 44395701,
83-3B	Developmental Toxicity - Rabbit	A,B,C,I	85079, 41530501
83-4	2-Generation Reproduction - Rat	A,B,C,I	43254705
84-2A	Gene Mutation (Ames Test)	A,B,C,I	156861,41496902,43983504,43983505
84-2B	Structural Chromosomal Aberration	A,B,C,I	147732,41496902
84-4	Other Genotoxic Effects	A,B,C,I	147732,147733
85-1	General Metabolism	A,B,C,I	41824307,41824308
85-2	Dermal Penetration	A,B,C,I	41824309, 42483103
OCCUPATIONAL/RESIDENTIAL EXPOSURE			

Appendix B: Data Supporting Guideline Requirements for the Reregistration of Vinclozolin

REQUIREMENT		USE PATTERN	CITATION(S)
132-1A	Foliar Residue Dissipation	A,B,C,I	42830001, 42830003, 43013003, 43343701, 43505901, 43528701,
132-1B	Soil Residue Dissipation	A,B,C,I	43013005
133-3	Dermal Passive Dosimetry Exposure	A,B,C,I	43013005, 43343702, 43983502, 44006101
ENVIRONMENTAL FATE			
161-1	Hydrolysis	A,B,C	41471006, 44025301
161-2	Photodegradation - Water	A,B,C	53092, 41471007, 42394706
161-3	Photodegradation - Soil	A,B,C	41471008, 44025302
162-1	Aerobic Soil Metabolism	A,B,C	136376, 43013001, 44025303
162-2	Anaerobic Soil Metabolism	A,B,C	41471009
162-3	Anaerobic Aquatic Metabolism	A,B,C	43013002, 43255801
163-1	Leaching/Adsorption/Desorption	A,B,C	41471010, 44025304, 44025305
163-2	Volatility - Lab	A,B,C	42513101
164-1	Terrestrial Field Dissipation	A,B,C	41538301, 42687601, 42717401, 43505907
165-1	Confined Rotational Crop	A,B,C	44301202, 44430001
165-4	Bioaccumulation in Fish	A,B,C	42847001
166-1	Ground Water - Small Prospective	A,B,C	Reserved
166-2	Ground Water - Small Retrospective	A,B,C	Reserved
166-3	Ground Water - Irrigated Retrospective	A,B,C	Reserved
RESIDUE CHEMISTRY			
171-4A	Nature of Residue - Plants	A,B,C,I	140835
171-4B	Nature of Residue - Livestock	B	44976801, 44988101
171-4C	Residue Analytical Method - Plants	A,B,C,I	43703303, 43703304
171-4D	Residue Analytical Method - Animal	B	43505902, 44025307
171-4E	Storage Stability	A,B,C	40297404
171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg	B	44976801, 44988101

Appendix B: Data Supporting Guideline Requirements for the Reregistration of Vinclozolin

REQUIREMENT		USE PATTERN	CITATION(S)
171-4K	Crop Field Trials	A,B,C	40297403, 43505905, 43505906, 42829801, 43703302, 44976801, 44988101
171-4L	Processed Food		44976801, 44988101

Appendix C: Citations Considered to be Part of the Data Base Supporting the Reregistration Decision (Bibliography)

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence

contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

MRID	CITATION

OCCUPATIONAL/RESIDENTIAL EXPOSURE

42342401 Rotondaro, A.; McKane, E. (1992) Worker Mixer, Loader, Applicator Exposure to Ronilan WP: Lab Project Number: EF-90-02. Unpublished study prepared by Pan-Agricultural Laboratories, Inc. 523 p.0133-3

42830001 Kludas, R.; Schimelfining, S. (1993) Dissipation of Dislodgeable Foliar Residues of Vinclozolin (Ronilan DF Fungicide) Applied to Orchards California and Georgia Sites: Lab Project Number: 92092: ER93017: 92086. Unpublished study prepared by Pan-Agricultural Labs, Inc. 122 p.0132-1

42830003 Baugher, D. (1993) Dislodgeable Foliar Residues, Exposure, and Margin of Safety Assessments for Harvester Reentry into Peaches Treated with Ronilan (Vinclozolin) 50 DF Fungicide: Lab Project Number: 37993: 63-VIN/93005: 93/5060. Unpublished study prepared by Orius Associates Inc. 16 p.

43013003 Rosenheck, L.; Schimelfining, S.; Clark, J. (1993) Worker Re-entry Exposure While Harvesting Strawberries Treated with Ronilan DF Fungicide in California: Lab Project Number:93/5140: 92092: ER93013. Unpublished study prepared by Pan-Agricultural Labs, Inc. and BASF Corp. 179 p.

43013004 Rosenheck, L.; Schimelfining, S.; Clark, J. (1993) Dissipation of Dislodgeable Foliar Residues of Vinclozolin (Ronilan DF Fungicide) Applied to Strawberry: Lab Project Number: 92092: ER93015: 92086. Unpublished study prepared byPan-Agricultural Labs, Inc. and BASF Corp. 183 p.

43013005 Rosenheck, L.; Schimelfining, S.; Clark, J. (1993) Dissipation of Dislodgeable Soil Residues of Vinclozolin (Ronilan DF Fungicide) Applied to Strawberry: LabProject Number: 92092: ER93016: 92086. Unpublished study prepared by Pan-Agricultural Labs, Inc. and BASF Corp. 134 p.

43343701 Kludas, R.; Schimelfining, S. (1994) Foliar Dislodgeable Residues of Vinclozolin (Ronilan 50% DF) in Turf, California and Pennsylvania Sites: Lab Project Number: 92086: 92092: ER93019. Unpublished study prepared by Pan-Agricultural Labs, Inc. 241 p. 0132-1

43343702 Rosenheck, L.; Schimelfining, S. (1994) Evaluation of Turf Re-entry Exposure in California to Broadcast Application of Ronilan DF: Lab Project Number: 92092: 92086: R93011.Unpublished study prepared by Pan-Agricultural Labs, Inc. 238 p.0133-3

MRID	CITATION
43505901	Morris, M.; Schimelfining, S. (1994) Dissipation of Dislodgeable Foliar Residues of Vinclozolin (Ronilan DF Fungicide) Applied to Orchards Pennsylvania Site (One of Three Sites): Lab Project Number: 94/5177: 92086: 92234. Unpublished study prepared by Pan-Agricultural labs, Inc. 99 p.
43528701	Sandberg, C.; Schimelfining, S. (1994) Foliar Dislodgeable Residues of Vinclozolin (Ronilan 50 (percent) DF) in Turf 1 Florida Site (one of three sites): Lab Project Number: 94/5178: 92092: ER93020. Unpublished study prepared byPan-Agricultural Labs, Inc. in cooperation with Agvise Labs. and Weed Systems, Inc. 181 p.
43983502	Baugher, D. (1996) Vinclozolin 50 DF: Exposure and Margins of Exposure for Snap Bean Irrigation Workers, Mixer/Loaders, and Applicators: Lab Project Number: 96/5033: 40696: 96010/VIN. Unpublished study prepared by Orius Associates, Inc. 19 p.0133-3
44006101	Baugher, D. (1996) Dermal Exposure of Mixer/Loaders Using Ronilan (Vinclozolin) DF Contact Fungicide: Aerial Application to Canola in Canada, 1995: Lab Project Number: 96/5014: 95092: ER-95046. Unpublished study prepared by Orius Associates Inc. 84 p.0133-3
44409404	Baugher, D. (1997) Vinclozolin: Reevaluation of Mixer/Loader and Applicator Exposure and Margins of Exposure: Lab Project Number: 42097V: 97018/VIN: 97/5375. Unpublished study prepared by Orius Associates Inc. 11 p.

ENVIRONMENTAL FATE

53092	Ohnsorge, U. (1980) Unsensitized Photolysis of Vinclozolin in Aqueous Solution: Lab. Communication No. 888. (Unpublished study received Oct 2, 1980 under 7969-53; prepared by BASF, AG, West Germany, submitted by BASF Wyandotte Corp., Parsippany, N.J.
136374	Huber, R.; Otto, S. (1979) Photolysis of 14C-Vinclozolin on Soil: Lab. Comm. No. 829. (Unpublished study received May 1, 1979 under 7969-53; prepared by BASF, AG, W. Ger., submitted by BASF Wyandotte Chemical Corp., Parsippany, NJ; CDL:098255-L)
136376	Huber, R.; Otto, S. (1978) Further Investigations into the Aerobic Soil Metabolism of BAS 352 F-14C (14C-vinclozolin): Bericht No. 1571. (Unpublished study received May 1, 1979 under 7969-53; prepared by BASF, AG, W. Ger., submitted by BASF Wyandotte Chemical Corp., Parsippany, NJ; CDL:098255-N)

MRID	CITATION
136377	Hamm, R. (1978) Degradation of 14C-vinclozolin (BAS 352 F) in Soil under Aerobic, Anaerobic, and Sterile Conditions: Report No. 1592. (Unpublished study received May 1, 1979 under 7969- 53; prepared by BASF, AG, W. Ger., submitted by BASF Wyandotte Chemical Corp., Parsippany, NJ; CDL:098255-O)
41471006	Grosshans, F. (1988) Hydrolysis of Vinclozolin (BAS 352F) in pH5,7, and 9 Aqueous Solutions at 25 [Degrees] C: Registration Document No. BASF: 88/0415. Unpublished study prepared by BASF Ag.
41471007	Huber, R. (1988) Amendment to Lab Report No. 1599: Sensitized Photolysis of [Carbon 14]-Vinclozolin in Water: Registration Document No. BASF: 88/0052. Unpublished study prepared by BASF Ag. 13 p.
41471009	Huber, R. (1989) Further Investigations into the Anaerobic Soil Degradation of Vinclozolin: Registration Document No. BASF: 89/0422. Unpublished study prepared by BASF Aktiengesellschaft. 91 p.0162-2
41471010	Ellenson, J. (1988) Soil Adsorption/Desorption of Vinclozolin: Registration Docuement No. BASF: 88/5063. Unpublished study prepared by BASF Corporation. 49 p.0163-1
41496904	Kaul, J. (1985) The Leaching Behaviour of [Carbon 14]-Vinclozolin and its Degradation Products in a Standard Soil Type 2. 1 (Loamy Sand) after a Degradation Period of 40 days: Lab Project No. 85/0501. Unpublished study prepared by BASF Aktiengesellschaft. 27 p.0163-1
41538301	Eubanks, M.; Clark, J. (1989) Vinclozolin (Ronilan Fungicide) Field Soil Dissipation Studies for Row Crop and Orchard Use: Summary, Analytical, and Field Studies, Volume I and II: Lab Project No. 89/5151. Unpublished study prepared by Morse Laboratories, Inc., and Hazleton Lab. America, Inc. 772 p.
41888904	Mckenna, E. ; Looper, G. (1991) Soil Adsorption/Desorption of [Carbon 14] Labeled Metabolites D (BF 352-31) and E (BF 352-23) of Vinclozolin (BAS 352 F): Lab Project Number: M9017/M9022: M9116. Unpublished study prepared by BASF Corp. 110 p.0163-1
42513101	Flynn, J.; Smith, D. (1992) Laboratory Volatility of Ronilan DF from Soil: Lab Project Number: 92/5150: 92038: 40188. Unpublished study prepared by ABC Labs. 48 p.
42687601	Anderson, S.; Clark, J. (1993) RONILAN Fungicide (BAS 352 12F) Soil Dissipation in Orchard and Strawberry Use Patterns: Analysis Through 540 Days-Final Report: Lab

MRID	CITATION
	Project Number: 93/5016: ER92074. Unpublished study prepared by Morse Labs.,Inc. in association with Horizon Labs., Inc. and Stewart Agricultural Research Services, Inc. 925 p.
42717401	Jackson, S. (1993) Vinclozoline (BAS 352 F) 1991 Turf Soil Dissipation: Analysis of Samples through 360 Days: Lab Project Number: 91066: 93/5012. Unpublished study prepared by BASF Corp. Chem. Div. in cooperation with Stewart Agri. Res. Serv., Inc., A.C.D.S., ADPEN Labs. Inc, Agvise Labs. and Horizon Labs. 473 p.
42847001	McKenna, E. (1993) Identification of Radioactive Residues in Water and Fish during Exposure of Bluegill Sunfish to (carbon 14)-Vinclozolin: Lab Project Number: 91145: M9208: 93/5066. Unpublished study prepared by BASF Corp. and Battelle. 138 p.
43013001	Honeycutt, R.; McKenna, E.; Goetz, A. (1993) Aerobic Soil Metabolism of (carbon 14)-Vinclozolin: Lab Project Number: 92033: M9301: 93/5101. Unpublished study prepared by BASF Corp. and Agvise Labs, Inc. 82 p.
43013002	McKenna, E.; Goetz, A. (1993) Anaerobic Aquatic Metabolism of (carbon 14)-Vinclozolin: Lab Project Number: 92034: M9302: 93/5144. Unpublished study prepared by BASF Corp. and Agvise Labs, Inc. 124 p.0162-3
43102601	Jackson, S. (1993) Vinclozolin (BAS 352 F) 1991 Turf Soil Dissipation: Analysis of Samples Through 360 days: Lab Project Number: 91066: 93/5176: ER92076. Unpublished study prepared by Adpen Labs, Inc; Agvise Labs; Horizon Labs, Inc; Stewart Agricultural Research Services, Inc. 61 p.0164-1
43255801	Wood, N. (1994) Additional Studies on the Identification of Radioactive Residues in an Anaerobic Aquatic System Treated with (carbon 14) Vinclozolin (Supplementary Study to that in Basf Report M 9302): Lab Project Number: 93189: M9337: M9302. Unpublished study prepared by BASF Corp. 19 p.
43505907	Barney, W. (1993) Vinclozolin Fungicide (BAS 352 40 F) Terrestrial Dissipation Study: Lab Project Number: 94/5107: 91038: RCN 91038. Unpublished study prepared by Environmental Technologies Institute, Inc.; Agvise; and Horizon Labs, Inc. 534 p.
44025301	Huber, R. (1996) Supplemental Information for Hydrolysis of Vinclozolin at pH 5 in Response to EPA Comments: Lab Project Number: 96/10149: 86/10337: 88/0415. Unpublished study prepared by BASF Aktiengesellschaft.15 p.

MRID	CITATION
44025302	Huber, R. (1996) Supplemental Information for Photolysis of Vinclozolin in Soil in Response to EPA Comments: Lab Project Number: 96/10150: 88/0521. Unpublished study prepared by BASF Aktiengesellschaft. 8 p.0162-1
44025304	Goetz, A. (1996) Response to Reviewer's Comments for Soil Adsorption/Desorption of Vinclozolin: (EFGWB Study 7--MRID 41471010): Lab Project Number: 96/5017: M9605: M8812. Unpublished study prepared by BASF Corp. 21 p.
44025305	Goetz, A. (1996) Response to Reviewer's Comments for Soil Adsorption/ Desorption of (carbon 14)-Labeled Metabolites D (BF 352-31) and E (352-23) of Vinclozolin (BAS 352 F): (EFGWB Study 8--MRID 41888904): Lab Project Number: 96/5015: M9604: M9116. Unpublished study prepared by BASF Corp. 22 p.
44025306	Williams, M. (1996) Storage Stability of Vinclozolin and Metabolites S, E, D, and B in Soil: Lab Project Number: 96/5085: A9504: HL10022. Unpublished study prepared by Horizon Labs, Inc. 242 p.
44430001	Wofford, J.; Abdel-Baky, S.; Riley, M. (1997) Vinclozolin Limited Rotational Crop Study for Succulent Beans: Lab Project Number: 97/5348: 95051: ER97017. Unpublished study prepared by BASF Corp. 224 p. {OPPTS 860.1850}
44301202	Wood, N. (1997) Confined Rotational Crop Study for Vinclozolin(Phenyl-U-(carbon 14)): Lab Project Number: 92132: M9416: 97/5092. Unpublished study prepared by BASF Corp. and Agvise Laboratories. 91 p.

RESIDUE CHEMISTRY

40019000	BASF Corp. (1986) Residue Data of Vinclozolin in Grape and Grape Juice. Compilation of 1 study.
40019001	Paulick, R. (1984) Determination of Vinclozolin and Its Metabolic Residues in Grape, Grape Juice, Wet Grape Pomace and Dry Grape Pomace Samples (with Introduction and Summary): Lab. Proj. IDPR-248R. Unpublished study prepared by BASF Analytical Laboratory. 29 p.
40297401	Paulick, R. (1987) Magnitude of the Residue of Vinclozolin and Metabolites in Raspberries: Registration Document # BASF: 87/5013. Unpublished compilation prepared by BASF Corporation Chemicals Division. 55 p.

MRID	CITATION
40297403	Paulick, R. (1987) Magnitude of the Residue of Vinclozolin and Metabolites in Onions: Registration Document # BASF: 87/5024. Unpublished study prepared by BASF Corporation Chemicals Division. Division. 53 p.
40297404	Paulick, R. (1987) Freezer Storage Stability of Vinclozolin and Its Metabolites, B, D, E and S in Grapes, Strawberries, Lettuce and Soil: Registration Document # BASF: 87/5018. Unpublished compilation prepared by BASF Corporation Chemicals Division. 48 p.
40403201	Paulick, R. (1987) Magnitude of the Residue of Vinclozolin in Grape Process Fractions: Registration Document # BASF: 87/5051. Unpublished study prepared by Morse Laboratories, Inc. 49 p.
40410201	Hawkins, D.; Kirkpatrick, D.; Dean, G.; et al. (1987) Biokinetics and Metabolism of [Carbon 14]-BAS 352F in the Goat: Rept. No. HRC/BSF 438/87234. Unpublished study prepared by Huntingdon Research Centre Ltd. 111 p.
40542901	Nelsen, T. (1980) Magnitude of the Residue of Vinclozolin and Metabolites in Chicory: BASF # 88/5005. Unpublished study prepared by BASF Agricultural Research Station, W. Germany. 60 p.
40854401	Hawkins, D.; Kirkpatrick, D.; Dean, G.; et al. (1987) The Metabolism of [Carbon 14]-Vinclozolin ([Carbon 14]-BAS 352F) in the Goat: Part II. Dosing of Additional Animals: Registration Document No. BASF: 88/0407. Unpublished study prepared by Huntingdon Research Centre, Ltd. 40 p.
40854402	Kohl, W. (1988) The Metabolism of [Carbon 14]-Vinclozolin in the Goat: Part III: Further Isolation and Identification of Metabolites: Registration Document No. BASF: 88/0408. Unpublished study prepared by BASF Ag. 85 p.
40826101	Fuchs, A. (1988) Magnitude of the Residue of Vinclozolin and Metabolites in Cucumber Samples from Spain: Registration Document No. BASF: 88/0140. Unpublished study prepared by BASF Agricultural Research Station. 58 p.
40826103	Fuchs, A. (1988) Magnitude of the Residue of Vinclozolin and Metabolites in Cucumber Samples from the Netherlands: Registration Document No. BASF: 88/0142. Unpublished study prepared by Agricultural Research Station. 90 p.
40854403	Mayer, F. (1987) Vinclozolin-Accountability of the DCA Method in Goat Tissues and Milk: Registration Document No. BASF: 87/0473. Unpublished study prepared by BASF Ruckstandsanalytisches Lab. 56 p.

MRID	CITATION
41040001	Roberts, N.; Fairly, C.; Gummer, J.; et al (1985) The Determination of Residues in the Eggs and Tissues of the Laying Hen Following Dietary Inclusion of Vinclozolin: Doc. No. 86/0482; Rept. No. BSF 432/86120. Unpublished study prepared by Huntingdon Research Centre, Ltd. 106 p.
41064501	Hawkins, D.; Kirkpatrick, D.; Dean, G.; et al. (1988) Biokinetics and Metabolism of (Carbon - 14)-Vinclozolin (Carbon - 14 BAS 352 F) in the Laying Hen: Part I: Registration Document No. BASF 88/0387. Unpublished study prepared by Huntingdon Research Centre Ltd. 84 p.
41064502	Hawkins, D.; Kirkpatrick, D.; Dean, G.; et al. (1988) Biokinetics and Metabolism of (Carbon - 14)-Vinclozolin (Carbon - 14 BAS 352F) in the Laying Hen: Part II: Registration Document No. BASF 88/0388. Unpublished study prepared by Huntingdon Research Centre Ltd. 52 p.
41080601	Walker, K. (1989) Ronilan: Vinclozolin Raw Agricultural Commodity of Snap and Lima Beans Treated with Ground, Aerial, and Irrigation Equipment in California, ..., and Wiscousin: Project ID: HLA 6737-115L. Unpublished study prepared by Hazleton Labora tories, Inc. 597 p.
41749601	Single, Y. (1990) GC Method For Residue Determination of Vinclozolin (BAS 352 F) and Its Metabolites in Bovine and Chicken Tissues Milk and Eggs: Lab Project Number: A9004. Unpublished study prepared by Huntingdon Research Center, Ltd. 38 p.
42593701	Becker, S. (1992) Magnitude of Residue of Ronilan WP Fungicide Applied to Onions: Lab Project Number: BAS 352 12 F/2: CAR127-89, 128-89, 129-89, and 174-90: EPL-BAS 137-006 & 137-012. Unpublished study prepared by California Agricultural Research, Inc. and EPL Bio-Analytical Services, Inc. 356 p.
42597901	Sears, L.; Vorndam, P. (1992) Method Validation Report: BASF Analytical Method A9207: Determination of Vinclozolin Metabolite BF 352-25 in Animal Matrices: Final Report: Lab Project Number: BASF-1170: 92/5181. Unpublished study prepared by Colorado Analytical R&D Corp. 77 p.
42622701	Fomenko, J. (1992) Testing of Vinclozolin Metabolites B, D, E, F, and S through FDA Multi-Residue Protocols A through E: Lab Project Number: 91017: A9216: 91162. Unpublished study prepared by Spectralytix, Inc. 412 p.

MRID	CITATION
42622702	Paulick, R. (1992) Freezer Storage Stability of Vinclozolin and its Metabolites, B,D,E, and S in Grapes, Strawberries, Lettuce and Peaches: Lab Project Number: 92/5118: A9209. Unpublished study prepared by BASF Corp. 119 p.
43272802	Thiem, D. (1994) Independent Method Validation, Analytical Method "HRC Modification of BASF Method No. 182 for the Analysis of Vinclozolin Residues in Animal Tissues": Lab Project Number: 94/5039: BASF-1145. Unpublished study prepared by BASF Corp.
43353101	Smith, M. (1994) Magnitude of the Residue of Vinclozolin and Its Metabolites in Leaf Lettuce, Raw Agricultural Commodity Samples: Lab Project Number: 94/5081: 91131: A9322. Unpublished study prepared by Stewart Agricultural Research Services, Inc., En-Cas Analytical Labs., and others. 176 p.
43353102	Smith, M. (1994) Magnitude of the Residue of Vinclozolin and Its Metabolites in Head Lettuce, Raw Agricultural Commodity Samples: Lab Project Number: 94/5082: 91132: A9323.Unpublished study prepared by Stewart Agricultural Research Services, Inc., En-Cas Analytical Labs., and others. 174 p.
43505902	Single, Y.; Sears, L. (1994) GC Method for Residue Determination of Vinclozolin (BAS 352 F) and Its Metabolites in Bovine and Chicken Tissues, Milk and Eggs: Amended Report: Lab Project Number: 94/5139: A9004A: A9004. Unpublished study prepared by Huntingdon Research Centre, Ltd. and Colorado Analytical Research and Development Corp. 70 p.
43505903	Sotock, G.; Jackson, S. (1994) Magnitude of Vinclozolin Residue for Snap Beans: WS vs DF Formulation-Ground Application: Lab 44988101 Ray, C.; Barney, W. (1993) Magnitude of the Residue of Vinclozolin and its Metabolites in Canola Seed Raw Agricultural Commodity Samples: Final Study Report: Lab Project Number: 93-0011: 91042: 91074. Unpublished study prepared by ADPEN Laboratories, Inc., and Environmental Technologies Institute, Inc. 181 p.
44025307	Thiem, D. (1996) Method Validation for the Analysis of Vinclozolin Metabolite BF 352-25 in Cow Liver Using BASF Method A9004: "GC Method for Residue Determinations of Vinclozolin (BAS 352 F) and Its Metabolites in Bovine and Chicken Tissues, Milk, and Eggs": Final Report: Lab Project Number: 96/5084: BASF-1215: A9447. Unpublished study prepared by Colorado Analytical Research & Development Corp. 49 p.

MRID	CITATION
44976801	Mikle, J.; Fedec, P. (1999) Canola Crush Test with Vinclozolin: Lab Project Number: 87/5216. Unpublished study prepared by POS Pilot Plant Corp. 28 p.
44992601	Wood, N. (1997) Metabolism of Vinclozolin (Phenyl-U-14C) in Lettuce: Lab Project Number: 92130: M9415: 97/5083. Unpublished study prepared by Agvise Labs. 66 p.
45006101	Scheppers, U. (1987) The Metabolism of BAS 352F in Grapes: Lab Project Number: 87/0306. Unpublished study prepared by BASF Aktiengesellschaft. 37 p.

PRODUCT CHEMISTRY

41471002	Guckel, B. (1987) Method of Determining the Vapor Pressure of Vinclozolin: Registration Document No. BASF: 87/0223. Unpublished study prepared by BASF AG. 29 p.
41471003	Patel, J. (1987) Partition Coefficient-(1-Octanol/water) of [Carbon 14]-Vinclozolin at 25 [Degrees] (+)(-) 1 [Degree] Celsius: Registration Document No. BASF: 87/5073. Unpublished study prepared by BASF Corp. 28 p.
41626801	Panek, E. (1990) Determination of the Color, Physical State, Odor, Melting Point, Bulk Density, and PH of Vinclozolin TGAI: Lab Project Number: F9020. Unpublished study prepared by BASF Corp. 11 p.
41626802	Fersch, J. (1990) Stability of Vinclozolin When Exposed to Heat, Sunlight, and Some Metals and Metal Ions: Lab Project Number: F9011. Unpublished study prepared by BASF Corp. 22 p.
41888901	Akers, R. (1991) Data Concerning the Product Identity, Beginning Materials and Manufacturing Process, and Formation of Impurities for the Technical Grade of Vinclozolin Fungicide: Lab Project Number: 91/5073. Unpublished study prepared by BASF Aktiengesellschaft. 44 p.
41888902	Akers, R. (1991) Report on the Preliminary Analysis, Certification of Limits, and Analytical Method to Verify Certified Limits for Vinclozolin, the Technical Grade of Active Ingredient of Ronilan Fungicide: Lab Project Number: 91/5074. Unpublished study prepared by BASF Aktiengesellschaft. 147 p.
41888903	Redeker, J. (1991) Determination of the Solubility of Vinclozolin in Organic Solvents at 20 Degrees Centigrade: Lab Project Number: 91/10055. Unpublished study prepared by BASF Aktiengesellschaft. 18 p.

MRID	CITATION

ECOLOGICAL EFFECTS

127750 Calmbacher, C. (1978) The Acute Toxicity of BWC Project VIII-1-H-145, BAS 352F to the Bluegill Sunfish: UCES Project No. 11506- 17-06. (Unpublished study received Apr 13, 1978 under 7969-EX-10; prepared by Union Carbide Corp., submitted by BASF Wyan-dotte Chemical Corp., Parsippany, NJ; CDL:097070-A)

134467 Morrissey, A. 1978 The Acute Toxicity of BAS 352 F BWC Project VIII-1-H-145 to the Water Flea Daphnia Magna Straws: UCES Project #11506-17-07. (Unpublished study received May 24, 1978 under 7969-EX-10; prepared by Union Carbide Corp., submitted by BASF Wyandotte Chemical Corp., Parsippany, NJ; CDL:097106-C)

136365 Fink, R.; Beavers, J.; Brown, R. (1978) Eight-day Dietary LC50 Bobwhite Quail--BAS 352 F: Project No. 147-115. Final rept. (Unpublished study received May 1, 1979 under 7969-53; prepared by Wildlife International Ltd., submitted by BASF Wyandotte Chemical Corp., Parsippany, NJ; CDL:098255-B)

136366 Fink, R.; Beavers, J.; Brown, R. (1978) Eight-day Dietary LC50--Mallard Duck--Bas 352 F: Project No. 147-116. Final rept. (Unpublished study received May 1, 1979 under 7969-53; prepared by Wildlife International Ltd., submitted by BASF Wyandotte Chemical Corp., Parsippany, NJ; CDL:098255-C)

136368 Calmbacher, C. (1978) The Acute Toxicity of Metabolite B, Vinclozolin (Bas 352) 99.5% Active Ingredient to the Bluegill Sunfish ...: UCES Proj. No. 11506-17-09; BWC V111-1-H-147. (Unpublished study received May 1, 1979 under 7969-53; prepared by Union Carbide Corp., submitted by BASF Wyandotte Chemical Corp., Parsippany, NJ; CDL:098255-E)

136370 Calmbacher, C. (1978) The Acute Toxicity of Metabolite B, Vinclozolin (Bas 352) to the Rainbow Trout ...: UCES Proj. No. 11506-17-08; BWC VIII-1-H-147. (Unpublished study received May 1, 1979 under 7969-53; prepared by Union Carbide Corp., submitted by BASF Wyandotte Chemical Corp., Parsippany, NJ; CDL:098255-G)

136371 Morrissey, A. (1978) The Acute Toxicity of Bas 352F to the Water Flea ... UCES Project # 11506-17-07; BWC Project VIII-1-H-145. (Unpublished study received May 1, 1979 under 7969-53; prepared by Union Carbide Corp., submitted by BASF Wyandotte Chemical Corp., Parsippany, NJ; CDL:098255-H)

136372 Morrissey, A. (1978) The Acute Toxicity of Metabolite B (Bas 352) Von Vinclozolin to the Water Flea ...: UCES Proj. No. 11506-17-11. (Unpublished study received May 1,

MRID	CITATION
	1979 under 7969-53; prepared by Union Carbide Corp., submitted by BASF Wyandotte Chemical Corp., Parsippany, NJ; CDL:098255-I)
137322	Fink, R.; Beavers, J.; Brown, R. (1978) Acute Oral LD50--Bobwhite Quail--Bas 352 F: Project No. 147-117. Final rept. (Unpublished study received May 1, 1979 under 7969-53; prepared by Wildlife International Ltd., submitted by BASF Wyandotte Chemical Corp., Parsippany, NJ; CDL:098255-A)
156861	Engelhardt, G. (1983) Report on the Study of Vinclozolin (Reg. No. 83 258) (ZNT Test Substance No.: 82/370) in the Ames Test: (Standard Plate Test and Preincubation Test with Salmonella typhimurium). Unpublished study prepared by BASF. 20 p.084-2156862 Hoorn, A. (1983) Mutagenicity Evaluation of Vinclozolin in the Rec Assay with Bacillus Subtilis: Final Report: Compound No. 83/233. Unpublished study prepared by Litton Bionetics. 10 p.
40992801	Hoxter, K.; Jaber, M. (1988) Vinclozolin: An Acute Contact Toxicity Study with the Honey Bee: 88/5134. Unpublished study prepared by Wildlife International Ltd. 21 p.0141-1
41325101	Munk, R. (1989) Report on the Study of the Acute Toxicity of Ronilan FL (BAS 352 3) in the Rainbow Trout: Lab Project Number: 89/0041. Unpublished study prepared by BASF AG. 46 p.
41679801	Gelbke, H. (1988) Reproduction Study with Vinclozolin in the Mallard Duck (Anas platyrhynchos L.) After Administration in the Diet: Testing for Male Fertility Project No. 72W466/86051: Lab Project Number: 88/0066. Unpublished study prepared by BASF Aktiengesellschaft. 435 p.
42827501	Johnson, A. (1993) Test Report 1-Generation Reproduction Study with Reg. No. 8358 (Vinclozolin) on the Mallard Duck (Anasplatyrhynchos) Administration in the Diet: Lab Project Number: 72W0022/929006: 93/10530: BSF 493/930701. Unpublished study prepared by Huntingdon Research Centre Ltd. 280 p.
42869801	Munk, R. (1993) Test Report: 1-Generation Reproduction Study with Reg. No. 83 258 (Vinclozolin) on the Bobwhite Quail(Colinus virginianus) Administration in the Diet: Lab Project Number: 93/10509: 71W0022/92005. Unpublished study prepared by BASF Aktiengesellschaft. 436 p.
44429901	Drottar, K.; Krueger, H.; Holmes, C. (1997) BAS 352 F: A 96-Hour Flow-Through Acute Toxicity Test with the Sheepshead Minnow (Cyprinodon variegatus): Lab Project

MRID	CITATION
	Number: 147A-155A: 96146: 97/5361. Unpublished study prepared by Wildlife International Ltd. 82 p.
44429902	Drottar, K.; Krueger, H.; Holmes, C. (1997) BAS 352 F: A 96-Hour Shell Deposition Test with the Eastern Oyster (Crassostrea virginica): Lab Project Number: 147A-156: 96144: 97/5360. Unpublished study prepared by Wildlife International Ltd. 73 p.
44429903	Drottar, K.; Krueger, H.; Holmes, C. (1997) BAS 352 F: A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysid (Mysidopsis bahia): Lab Project Number: 147A-154A: 96145: 97/5359. Unpublished study prepared by Wildlife International Ltd. 76 p.

TOXICOLOGY

75474	Leuschner, F. (1979) Acute Inhalation Toxicity Study: Preparation Reg. No. 83258 (Vinclozolin). (Unpublished study received Feb 11, 1981 under 7969-53; prepared by Laboratorium fur Pharmakologie und Toxikologie, West Germany, submitted by BASF Wyandotte Corp., Parsippany, N.J.; CDL:244529-A)
80451	Gelbke, ? (1979) Study of the Sensitization Effect on Guinea Pigs: Maximization Test. (Translation; unpublished study received Aug 4, 1981 under 7969-53; prepared by BASF, West Germany, submitted by BASF Wyandotte Corp., Parsippany, N.J.; CDL:245833-A)
85079	Cozens, D.D.; Edwards, J.A.; Leeming, N.M.; et al. (1981) Effect of Vinclozolin on Pregnancy of the New Zealand White Rabbit: HRC Report No. BSF/380/381/81357. (Unpublished study received Oct 14, 1981 under 1E2457; prepared by Huntingdon Research Centre, England, submitted by BASF Wyandotte Corp., Parsippany, N.J.; CDL:070400-A)
86336	Hofmann, H.T.; Freisberg, K.O. (1973) Report on Acute Oral Toxicity Trial of 3-(3,5-Dichloro-phenyl)-5-methyl-5-vinyl-1,3-oxazolidine-2,4-dione in Rats. (Unpublished study received Mar 17, 1978 under 7969-EX-10; submitted by BASF Wyandotte Corp., Parsippany, N.J.; CDL:096963-K)
86339	Hildebrand, B. (1977) Acute Dermal Toxicity of Reg. No. 83258 (Vinclozolin) to the Rat. (Unpublished study received Mar 17, 1978 under 7969-EX-10; prepared by BASF AG, West Germany, submitted by BASF Wyandotte Corp., Parsippany, N.J.; CDL:096963-N)

MRID	CITATION
86340	Hildebrand, B. (1977) Primary Skin Irritation of Reg. No. 83258 (Vinclozolin) on the Intact and Scarified Dorsal Skin of White Rabbits. (Unpublished study received Mar 17, 1978 under 7967- EX-10; prepared by BASF AG, West Germany, submitted by BASF Wyandotte Corp., Parsippany, N.J.; CDL:096963-O)
86341	Hildebrand, B. (1977) Primary Irritation of Reg. No. 83258 (Vinclozolin) to the Eye of White Rabbits. (Unpublished study received Mar 17, 1978 under 7969-EX-10; prepared by BASF AG, West Germany, submitted by BASF Wyandotte Corp., Parsippany, N.J.; CDL: 096963-P)
143482	Moulton, R. (1984) Acute Dermal Toxicity Test in Rabbits: S. A. No. 334484. Unpublished study prepared by Scientific Associates, Inc. 11 p.
147732	Cifone, M. (1984) Evaluation of Vinclozolin in the Primary Rat Hepatocyte: Unscheduled DNA Synthesis Assay: Final Report: Project No. 20991. Unpublished study prepared by Litton Bionetics, Inc. 15 p.
147733	Witterland, W. (1984) Mutagenicity Evaluation of Vinclozolin (83/ 233) in the Mouse Lymphoma Forward Mutation Assay: Final Report: Genetics Assay No. E-9176. Unpublished study prepared by Litton Bionetics, Netherlands. 19 p.
156861	Engelhardt, G. (1983) Report on the Study of Vinclozolin (Reg. No. 83 258) (ZNT Test Substance No.: 82/370) in the Ames Test: (Standard Plate Test and Preincubation Test with Salmonella typhimurium). Unpublished study prepared by BASF. 20 p.084-2156862 Hoorn, A. (1983) Mutagenicity Evaluation of Vinclozolin in the Rec Assay with Bacillus Subtilis: Final Report: Compound No. 83/233. Unpublished study prepared by Litton Bionetics. 10 p.
40859501	Hellwig, J. (1987) Report on the Study of the Toxicity of Vinclozolin in Beagle Dogs after a 12-month Administration via the Diet: Document No. 87/0447. Unpublished study prepared by BASF Aktiegensellschaft. 1136 p.
41325001	BASF Corp. (1989) Prenatal Toxicity Study in Rats (Dermal Application): Lab Project Number: 34R0375/88074. Unpublished study. 35 p.
41413001	Gelbke, H. (1990) Study of the Prenatal Toxicity of Reg. No. 83 258 in Rats after Dermal Application: [Vinclozolin]: Project Nos. 90/0025; 34R0375/88074. Unpublished study prepared by BASF Aktiengesellschaft, Dept. of Toxicology. 457 p.

MRID	CITATION
41471004	Leuschner, F. (1977) 3-Weeks Toxicity of an Oxazolidine Derivative, Batch 83 258 (Vinclozolin) called for Short "Oxa"-in NZW Rabbits by Local Application: Registration Document No. BASF: 77/0015. Unpublished study prepared by Laboratorium fur Pharmakologie und Toxikologie. 139 p.083-1
41471005	Gelbke, H.; Engelhardt, G. (1983) Report on the Study of Vinclozolin (Reg No. 83/258) (ZNT Test Substance No. 82/370) in the AMES Test: Registration Docuement No. BASF 83/0228. Unpublished study prepared by BASF Aktiengesellschaft, Dept. of Toxicology. 22 p.
41496902	Murli, H. (1989) Report on the Mutagenicity Test on ... (Vinclozolin) in vitro Cytogenetic Assay Measuring Chromosomal Aberration Frequencies in Chinese Hamster Ovary (CHO) Cells: Lab Project No. 89/0073. Unpublished study prepared by Hazleton Laboratories America, Inc. 44 p.
41530501	Gelbke, H. (1990) Report on the Supplementary Study of the Prenatal Toxicity of Reg. No. 83 258 (Vinclozolin) in Rabbits after Oral Administration (Gavage) Project No.:38R0375/88062: Lab Project Number: 90/0051. Unpublished study prepared by BASF Aktiengesellschaft, Dept. of Toxicology. 385 p.
41709301	Gelbke, H. (1990) Report on the Study of the Prenatal Toxicity of (...) (Vinclozolin) in Rabbits after Oral Administration (Gavage): Final Report: Lab Project Number: 38R0375/88062: 90/0050. Unpublished study prepared by BASF Ag. 52 p.
41824302	Hildebrand, B. (1990) Report Study on the Oral Toxicity of (...) (Vinclozolin) in B6C3F1 Mice Administration in the Diet Over 3 Months: Lab Project Number: 90/0422: 53S0375/88025. Unpublished study prepared by BASF Ag, Dept. of Toxicology. 102 p.
41824307	Hawkins, D. (1990) The Biotransformation of [carbon 14]-Vinclozolin in the Rat: Lab Project Number: 90/0514. Unpublished study pre pared by Huntingdon Research Centre, Inc. 103 p.085-1
41824308	Hawkins, D. (1990) The Biokinetics of [carbon 14]-Vinclozolin in the Rat: Lab Project Number: 90/0544. Unpublished study prepared by Huntingdon Research Centre, Ltd. 153 p.
41824309	Hawkins, D. (1991) The Dermal Absorption of [carbon 14]-Vinclozolin in the Rat: Lab Project Number: 91/10059. Unpublished study prepared by Huntingdon Research Centre, Ltd. 100 p.

MRID	CITATION
42393701	Kieczka, H. (1987) Report on the Open Epicutaneous Test (OET) for the Sensitizing Potential of BAS 352 F (Ronilan FL) in the Guinea Pig, dated January 13, 1987: Lab Project Number: 87/0012. Unpublished study prepared by BASF Aktiengesellschaft, Dept. of Tox. 35
42483103	Cameron, B.; Jack, L.; Van Ravenzwaay, B. (1992) In vitro Percutaneous Absorption of [Carbon 14]--Reg No. 83258 (Vinclozolin): A Comparison Using Rat and Human Epidermis Plus Summary: Lab Project Number: IRI 150582. Unpublished study prepared by Inveresk Research International. 82 p.
42581301	Hellwig, J. (1992) Report Reproduction Study with Reg. No. 83258 (Vinclozolin) in Rats Continuous Dietary Administration over 2 Generations (2 Litters in the First and 2 Litters in the Second Generation): Lab Project Number: 92/11251: 71R0375/88053. Unpublished study prepared by BASF Aktiengesellschaft Department of Toxicology. 2901 p.
42714001	Schilling, K. (1993) Evaluation of Ophthalmology Findings Recognized within Various Rat Feeding Studies with Vinclozolin: Lab Project Number: 93/5027: 71S0375/88026. Unpublished study prepared by BASF Aktiengesellschaft. 42 p.
43170501	Gray, L.; Kelce, W.; Laws, S.; et al. (1993) Internal EPA Report on: Antiandrogenic Effects of the Fungicide Vinclozolin on Sex Differentiation of the LE Hooded Rat: Lab Project Number: 68D20056. Unpublished study prepared by USEPA. 100 p.
43254701	Mellert, W. (1994) Toxicology Study Report: Chronic Toxicity Study with Reg. No. 83 258: Vinclozolin in Rats Administration in the Diet for 24 Months: Lab Project Number: 71S0375/88026: 94/10287. Unpublished study prepared by BASF Aktiengesellschaft Dept. of Toxicology. 1798 p.
43254702	Mellert, W. (1994) Toxicology Study Report: Second Chronic Toxicity Study with Reg. No. 83 258: Vinclozolin in Rats Administration in the Diet for 24 Months: Lab Project Number: 71S0375/88109: 94/10288. Unpublished study prepared by BASF Aktiengesellschaft Dept. of Toxicology. 1161 p.
43254703	Mellert, W. (1994) Toxicology Study Report: Carcinogenicity Study with Reg. No. 83 258: Vinclozolin in Wistar Rats Administration in the Diet for 24 Months: Lab Project Number: 71S0375/88105: 94/10279. Unpublished study prepared by BASF Aktiengesellschaft Dept. of Toxicology. 1731 p.

MRID	CITATION
43254704	Mellert, W. (1994) Toxicology Study Report: Carcinogenicity Study with Reg. No. 83 258: Vinclozolin in C57BL Mice Administration in the Diet for 18 Months: Lab Project Number: 80S0375/88112: 94/10278. Unpublished study prepared by BASF Aktiengesellschaft Dept. of Toxicology. 2257 p.
43254705	Hellwig, J. (1994) Toxicology Study Report: Second Reproduction Toxicity Study with Reg. No. 83 258: Vinclozolin in Rats Continuous Dietary Administration over 2-Generations (2 Litter in Each Generation): Lab Project Number: 70R0375/88119: 94/10280. Unpublished study prepared by BASF Aktiengesellschaft Dept. of Toxicology. 1345 p.
43259001	van Ravenzwaay, B. (1994) Toxicology Study-Report: Information on the Long-Term Toxicity of Reg. No. 83 258 (Vinclozolin) in Rats and Mice: Lab Project Number: 94/10293. Unpublished study prepared by BASF Dept. of Toxicology. 51 p.
43703301	Hellwig, J. (1995) Study of the Prenatal Toxicity of REG No. 82258 (Vinclozolin) in Wistar Rats After Dermal Application: Lab Project Number: 34R0375/88124: 95/10450. Unpublished study prepared by BASF Aktiengesellschaft. 256 p.
43983504	Engelhardt, G. (1995) Cytogenetic Study in vivo of Vinclozolin in NMRI Mice Micronucleus Test Single Intraperitoneal Administration: Lab Project Number: 94/11176: 26M0375/884498. Unpublished study prepared by BASF Aktiengesellschaft. 42 p.
43983505	Engelhardt, G. (1995) Cytogenetic Study in vivo of Vinclozolin in CD-1 Mouse Micronucleus Test Single Intraperitoneal Administration: Lab Project Number: 95/11174: 26M0375/884499. Unpublished study prepared by BASF Aktiengesellschaft. 42 p.084-2
44006102	Mellert, W.; Deckardt, K.; Kaufmann, W.; et al. (1995) (Vinclozolin)--Reversibility of Selective Findings in Wistar Rats: Dietary Administration for 3 Months and 1-Month and 3-Month Recovery Periods: Lab Project Number: 95/11159: D-67056: 39S0375/88116. Unpublished study prepared by BASF Aktiengesellschaft. 841 p.
44395701	Hellwig, J.; Hildebrand, B. (1997) Report: Reg. No. 83258--Pre-/Postnatal Toxicity Study in Wistar Rats After Oral Administration (Gavage) (Reporting Period: Until Weaning of the F1 Pups on Day 22 Post Partum): Lab Project Number: 60R0375/88126: 97/11003. Unpublished study prepared by BASF Aktiengesellschaft. 203 p.
44395702	Hellwig, J.; Hildebrand, B. (1997) Report: Reg. No. 83258--Pre-/Postnatal Toxicity Study in Long Evans Rats After Oral Administration (Gavage) (Reporting Period: Until Weaning

MRID	CITATION
	of the F1 Pups on Day 22 Post Partum): Lab Project Number: 60R0375/88125: 97/11002. Unpublished study prepared by BASF Aktiengesellschaft. 278 p.
44430301	Hildebrandt, P. (1997) Pathology Working Group Report: Vinclozolin: 24-Month Chronic Toxicity and Carcinogenicity Studies in Wistar Rats: Lab Project Number: 71S0375/88026: 71S0375/88105: 97/11184. Unpublished study prepared by Pathco, Inc. 374 p.
44501002	Hellwig, J.; Gembardt, C.; Gelbke, H. (1998) Report: Reg. No. 83 258--Pre-/Postnatal Toxicity Study in Wistar Rats after Oral Administration (Gavage): Lab Project Number: 60R0375/88126:98/10077: 88126. Unpublished study prepared by BASF Aktiengesellschaft. 371 p.
44501003	Lam, W. (1998) Structure Reactivity Consideration of 4-Chloroaniline and 3,5-Dichloroaniline: Summary Report. Unpublished study prepared by BASF Aktiengesellschaft. 15 p.
44501004	Engelhardt, G.; Hoffmann, H. (1997) Report Salmonella Typhimurium Reverse Mutation Assay with Norharman: Two Screening Studies for the Comparison of 3,5-Dichloroaniline and 4-Chloroaniline: Lab Project Number: 97/11005: EN-KRS0101: 40M0332/974115. Unpublished study prepared by BASF Aktiengesellschaft. 32 p.

Appendix D: Generic Data Call-In

See attached table for a list of generic data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions is being sent to registrants under separate cover.

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 12/31/00

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary

1. Company name and Address	2. Case # and Name 2740 Vinclozolin Chemical # and Name 113201 Dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione (90A	3. Date and Type of DCI GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
62-2 *	Certification of limits					all		12 mos.	
162-1 *	Aerobic soil metabolism		Y			ABCI		24 mos.	
163-1 *	Leach/adsorp/desorption					ABCI		12 mos.	

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
2740 Vinclozolin
Chemical # and Name
113201 Dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione (9CA

GUIDELINE	COMMENT
62-2	Specify values for the nominal concentration and the upper certified limit of the active ingredient.
162-1	Data for individual analytes (metabolites B,D, and E) in soil are needed.
163-1	Metabolite B: Kd values for four soils should be submitted.

Appendix E: Product Specific Data Call-In

See attached table for a list of product-specific data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions is being sent to registrants under separate cover.

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
2740 Vinclozolin

EPA Reg. No. NNNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
830.1550	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1600	Description of materials used to produce the product (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1620	Description of production process (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1650	Description of formulation process (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1670	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1700	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1750	Certified limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1800	Enforcement analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6302	Color (17)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6303	Physical state (17)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6304	Odor (17)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
2740 Vinclozolin

EPA Reg. No. NNNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
830.7000	pH (9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.7050	UV/Visible absorption					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.7100	Viscosity (13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.7300	Density					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6314	Oxidation/reduction: chemical incompatability (10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6315	Flammability (11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6316	Explodability (12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6317	Storage stability					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6319	Miscibility (14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6320	Corrosion characteristics					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6321	Dielectric breakdown voltage (15)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
	Acute Toxic - Regular Chemical								
870.1100	Acute oral toxicity (1,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
870.1200	Acute dermal toxicity (1,2,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
870.1300	Acute inhalation toxicity (3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
870.2400	Acute eye irritation (2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
870.2500	Acute dermal irritation (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
870.2600	Skin sensitization (4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2740 Vinclozolin

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product. [NOTE: If a product is a 100 percent repackage of another registered product, registrants are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

A - Terrestrial food crop	B - Terrestrial food feed crop	C - Terrestrial nonfood crop	D - Aquatic food crop	E - Aquatic nonfood outdoor
F - Aquatic nonfood Industrial	G - Aquatic nonfood residential	H - Greenhouse food crop	I - Greenhouse nonfood crop	J - Forestry
K - Residential outdoor	L - Indoor food	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
4 To support registration of an MP or EP, whether produced by an integrated system or not, the technical grade of Active Ingredient must be analyzed. If the technical grade of Active Ingredient cannot be isolated, a statement of composition of the practical equivalent of the technical grade of Active Ingredient must be submitted. Data on EPs or MPs will be required on a case-by-case basis.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.
17 Not required unless efficacy data are required.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2740 Vinclozolin

Footnotes (cont.):

37 Testing of the EP dilution in addition to the EP or MP is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

Appendix F: EPA Batching of End Use Products for Meeting Data Requirements for Reregistration

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products, the Agency batches products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note the Agency is not describing batched products as "substantially similar" since some products with in a batch may not be considered chemically similar or have identical use patterns. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should need arise.

Three currently-registered products were found which contain ***Vinclozolin*** as the active ingredient. No formal batching is necessary because the formulations are dissimilar. Each product must be supported by product-specific data or other forms of acceptable data.

No Batch	EPA Reg. No.	Percent active ingredients	Formulation Type
	7969-57	96.0	Solid
	7969-62	43.0	Liquid
	7969-85	50.0	Solid

Appendix G: List of Registrants Sent This Data Call-In

United States Environmental Protection Agency
Washington, D. C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 2740 Vinclozolin

Co. Nr.	Company Name	Additional Name	Address	City & State	Zip
007969	BASF CORP	AGRICULTURAL PRODUCTS	BOX 13528	RESEARCH TRIANGLE PARK	27709
011179	SANTA CRUZ COUNTY AGRICULTURE COMM		175 WESTRIDGE DRIVE	WATSONVILLE CA	95076
058185	SCOTTS-SIERRA CROP PROTECTION CO	ATTN: VINCENT SNYDER, JR	14111 SCOTTSLAWN RD	MARYSVILLE OH	43041
063201	CALIFORNIA VEGETABLE SPECIALTIES I	AGRICULTURAL CHEMICALS	15 POPPYHOUSE RD	RIO VISTA CA	94571

Appendix H: List of Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

   DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

   If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet: at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf.
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.